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Accelerating the Fight Against Chickenpox and Shingles

by Rochelle Runas, ISPE Technical Writer

This is a case study on Merck's Vaccine Bulk Manufacturing Facility (VBF) Program of Projects, Overall Winner of the 2012 Facility of the Year Awards.

Introduction

In 2008, Merck & Co., Inc. realized that in less than four years, patients would need more than double the vaccine for chickenpox and shingles. If Merck did not increase production capacity, millions of people a year would suffer from these diseases.

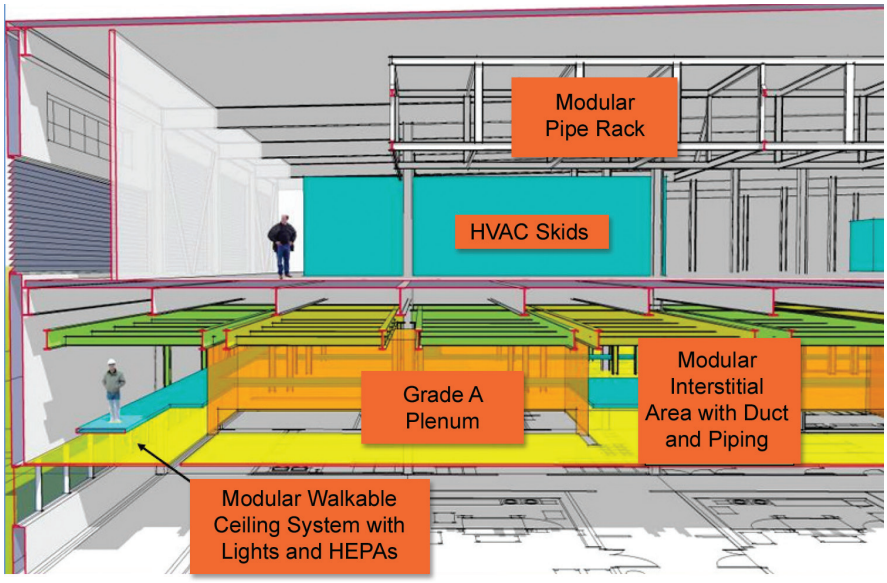
In order to increase production, Merck would have to design, build, and license a new facility that was larger than the existing manufacturing – and do it in less than four years. Merck had never constructed and licensed a sterile vaccine manufacturing facility that large or that fast before. In addition, an analysis conducted by an industry benchmarking group indicated a less than 3% chance for delivering such a facility on time.

But, Merck succeeded, delivering the Vaccine Bulk Manufacturing Facility (VBF) Program of Projects – Overall Winner of the 2012 Facility of the Year Awards. Not only did they double the output of much needed vaccines; they delivered a facility faster than industry norms. This article presents the strategies Merck used in their race to achieve and surpass what at first seemed impossible.

Project Overview

The existing Merck site located in Durham, North Carolina, USA was chosen for the Varicella Bulk Manufacturing Facility (VBF) Program of Projects. The $315 million VBF project comprises four integrated and simultaneously designed and constructed buildings: the Virus Vaccine Bulk Facility Building, the Energy Center Expansion, the Material Management Support Facility (MMSF) Expansion, and the Operational Support Facility (OSF) Expansion. The 214,000-square-foot manufacturing facility supports Merck's Varicella product franchise, which includes the Varivax® vaccine for chickenpox and the Zostavax® vaccine for shingles.

"I think what caught the judges' eyes is that it's a very large facility, completed in a very rapid time frame, and is now manufacturing saleable product," said Brian Morrissey, Associate Director, Engineering, Merck Manufacturing



Modular types inserted into the pre-fabricated building shell.

Vaccine Bulk Manufacturing Facility – 214,000 SF
• Classified space (80, 000 sf), unclassified space, mechanical spaces, and HVAC systems • Grade A – 6,000 sf • Grade B – 28,000 sf • Grade C – 23,100 sf • Grade D – 23,400 sf • (2) Bulk manufacture Suites – (12) isolators • Pre-position of support space for expansion - Sterile Supply, Media, Cell, Decon • Clean Utility Generation and Distribution • Clean In Place for PSF • Biowaste Inactivation • Automation (DeltaV, MES, Business Systems) • Locker facility • Operations office and meeting space - Document Control Center • Spine Extension
Energy Center
• Bldg expansion, 4,000 SF • (2) 1500 T Chilled water chillers • (2) 700 T Glycol chillers • (3) substations + (1) 2 MW emerg. generator • (1) additional air compressor • (1) additional 50,000 #/hr boiler
MMSF
• Two bay expansion, ~24,000 SF • 2 to 8°C Cold storage, -20°C freezer, and -70°C freezer expansion • Ambient storage expansion • VVTE Lab Expansion, 1 bay • GMP lab space for assay tests • Incoming material sampling and inspection
OSF
• 2 story addition architecturally matched to existing OSF building ~ 18,500 SF • Cafeteria and offices

VBF Program – scope summary.

Division. "We were able to go right from construction, to Commissioning and Qualifications, to PV lots, to submitting a license. It all went very smooth."

The Merck team contributes their success to a rapid design, build, deliver approach supported by three main strategies:

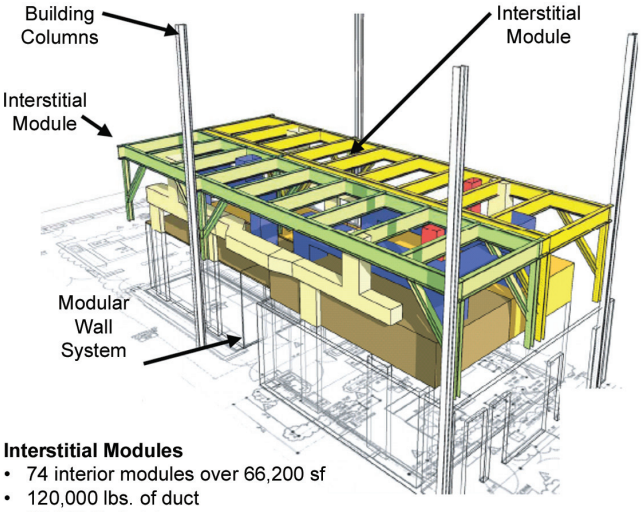
- Innovative (Hybrid) Modular Execution
- "One Team" Project Delivery
- Lean Six Sigma Approach to Commissioning, Qualification, Validation (CQV)

Going Modular for Speed

Early in the project during schedule and scope review, it was quickly determined that with a traditional stick-built approach, the project would not meet the required dates. The critical path, with activities typically carried out sequentially, was months too long. The Merck team's solution: decouple design and construction of the building envelope (foundation and shell) from the interior process components and execute them as parallel activities.

Essentially, the building envelope was stick-built using an economical pre-engineering building, and modular construction was used for the following major interior components:

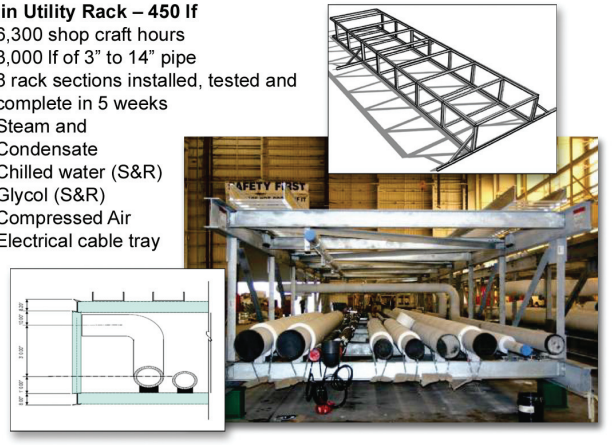
- Interstitial Modules
- Skid mounted AHU and Duct Piping
- Interior Pipe Racks



Interstitial Modules
- 74 interior modules over 66,200 sf
- 120,000 lbs. of duct
- 32,600 lf of piping
- 44,000 lf of electrical raceway
- Installed hanging, walkable ceiling system
- Light fixtures and HEPA housings installed
- 20% to 25% labor efficiency
- 154,000 shop craft hours
- Safe, clean, environmentally controlled working area

Interstitial Module Summary.

Main Utility Rack – 450 lf
- 6,300 shop craft hours
- 3,000 lf of 3" to 14" pipe
- 8 rack sections installed, tested and complete in 5 weeks
- Steam and Condensate
- Chilled water (S&R)
- Glycol (S&R)
- Compressed Air
- Electrical cable tray



Pipe Rack Summary.

HVAC Skids
- Supply and return risers with devices and wiring
- AHU's shipped and rigged in place in one piece with devices, valving, and wiring
- 14 AHU's
- 32 Mechanical duct and piping skids
- 126,000 lbs. of duct
- 12,500 lf of pipe
- Installed in facility in 8 weeks

HVAC/Duct Skid Summary.

- Modular Clean Room Walls and Ceiling

"This is one of the achievements I'm most proud of – use of this hybrid modularization technology," said Morrissey. "It worked very well and saved us several months." One hundred twenty-eight modular units, representing 270,000 craft hours, were fabricated off-site and executed in parallel with the on-site construction. The approach reduced the schedule by five months and saved more than $43 million in project and business spending.

"One Team"

The project team was organized into "One Team" that included all members – owners, engineers, contractors, and vendors. This was a critical aspect of delivering a hyper track project because a lot of information needed to flow quickly, requiring a single, integrated project team. This was no small challenge given the 50 equipment suppliers and 46 subcontractors required to execute the project.

Given the scheduling and coordination complexities, it was decided to align the project organization around the principles of Lean project delivery. The team utilized Lean Six Sigma tools and found partners that were both amenable to it and willing to take on a significant challenge. In this approach, the team utilized collaborative relationships with suppliers and subcontractors, facilitated Kaizan brain storming sessions, used A3 decision making, and construction "pull" leadership to minimize engineering deliverables to only the absolute minimum design details necessary to obtain building permits and construction quality drawings. This approach resulted in a streamlined design process that optimized both constructability input and fabrication details.

"One of the factors that allowed us to accomplish this project in the 24 months from charter to OQ complete, was that we were very close with our engineering and construction management partners," said Morrissey. "We all sat in one trailer in one place to get this project done. Whenever we came upon obstacles, we didn't point fingers at each other; we worked through it as One Team. I think that helped quite a bit."

Lean Six Sigma Approach to CQV

Due to the large scale and hyper track schedule, the team again reached into their Lean Six Sigma tool box for their Commissioning, Qualification, Validations (CQV) approach and formed several teams to address each of the main operational areas or production suites of the manufacturing facility. These "Suite Teams" were made up of representatives from Technical Operations, Production, and support from Maintenance, Quality, Process Engineering, Automation, Validation, and/or Commissioning and Construction.

The collaborative approach allowed the teams to discover system deficiencies during start-up, determine and address root causes, and continue testing with minimal schedule disruption.

The project also utilized an enhanced turnover process following the *ISPE Baseline® Guide: Volume 5 – Commissioning and Qualification* and other industry C&Q best practices. Integration of data for turnover of systems started early. Engineering developed Vendor Document Requirements that were coordinated with the Merck Project Database that allowed for pre-population of equipment,

Key Project Participants

Designer/Architect: Jacobs® (NYSE:JEC) Pasadena, California, USA
Engineer: John R. McAdams Company, Inc., Durham, North Carolina, USA
Construction Manager and Main/General Contractor: Jacobs® (NYSE:JEC) Pasadena, California, USA
Piping Subcontractor: Dynamic Systems Incorporated, Morrisville, North Carolina, USA
HVAC Subcontractor: Environmental Air Systems, Inc., Greensboro, North Carolina, USA
Automation and Control Supplier: Siemens Industry, Inc., Building Technologies Division, Morrisville, North Carolina, USA

Major Equipment Suppliers:
Clean Rooms: Advance TEC, Richmond, Virginia, USA
Robot Integrator: Advanced Automation, a Doefer Company, Greenville, South Carolina, USA
Parts Washer: Getinge USA, Inc., Rochester, New York, USA
Cold Rooms: Luwa, Inc., Holliston, Massachusetts, USA
PSF Skids: Cotter Brothers, Danvers, Massachusetts, USA
Autoclaves: Fedegari Technologies Inc., Dublin, Pennsylvania, USA

Varicella (Chickenpox) and Herpes Zoster (Shingles)

Varicella, commonly known as chickenpox, is caused by the varicella-zoster virus (a member of the herpesvirus family), which was first identified in 1952. The same virus, when reactivated from a latent state in nerve cells, causes another disease – herpes zoster, or shingles. In most populations, varicella is a disease of children, and herpes zoster a disease of elderly people. However, the epidemiology of disease can vary, especially in tropical countries where infection and varicella may occur more often in older age groups. The hallmark symptom of varicella is an itchy rash, consisting of blister-like vesicles.

The varicella-zoster virus only infects humans. It spreads from person-to-person through direct contact, or from the virus being sneezed or coughed into the air or released from the vesicles on the skin. Generally, varicella is a mild disease. However, complications, which can be sometimes severe, occur in about 10% of cases, mostly in adolescents and adults (who are 30 to 40 times more likely than children to die from severe complications). Varicella infection itself induces lifelong immunity to chickenpox in virtually everyone whose immune system is working normally.

Herpes Zoster (Shingles) – Same Virus, Different Disease

In 10 to 20% of children infected with varicella, the virus takes up residence in nerve cells, where it lies dormant for several decades, until a lowering of the host's immune defenses (as a result of aging, disease, or immunosuppressive treatment) allows it to awaken, begin replicating, and precipitate herpes zoster disease, or shingles as it is commonly known. In the US alone, there are an estimated 1 million cases each year and nearly 1 out of 3 will develop shingles, according to the US Centers for Disease Control and Prevention.

Herpes zoster is characterized by a painful blistering rash along the distribution of the infected nerve cells. In about 15% of patients, though, pain and numbness in the area of the rash can last for weeks or months. The pain can be severe and highly disabling, both physically and mentally. Itching, which may fluctuate from mild to intense, adds to the person's discomfort.

Merck's Zostavax® is the only shingles vaccine on the market. It was approved by the US FDA in 2006 for use in persons 60 years of age and older, and in 2011 for persons 50 through 59 years of age.

Little is known about the burden of varicella in developing countries. However, in 2006, an estimate based on the incidence of varicella in industrialized countries gave a total worldwide estimate of 90 million cases a year.

Vaccination is the only way to protect whole communities and populations from varicella, and possibly from herpes zoster. A safe and effective vaccine against varicella has been available in several formulations (including Merck's Varivax®, licensed in the US in 1995) since the mid-1970s. And in 2005, Merck's ProQuad®, a combination measles-mumps-rubella-varicella vaccine, came on to the market. The single-antigen (i.e., containing varicella virus only) vaccine has been administered to millions of children, adolescents, and adults in many countries. In children, a single dose produces anti-varicella antibodies in about 95% of recipients and protects them against the disease. Furthermore, at least 90% of people given the vaccine within three days of being exposed to the virus are protected against developing the disease. In those who develop disease after vaccination, it is much milder than in unvaccinated individuals.

The effectiveness and cost-effectiveness of the vaccine have prompted several industrialized countries in Asia, Europe, and North America to adopt it in their routine child immunization programs. In 1995, the US became the first country to adopt the vaccine into its routine immunization program and by 2002 saw a 74 to 92% drop in child deaths from varicella and an 88% drop in hospitalizations due to the disease. The use of the vaccine has also been shown to be cost-effective in the US. Some epidemiologists believe that widespread routine administration of the varicella vaccine in children could eventually lead to the virtual disappearance of the disease.

Source:
- State of the world's vaccines and immunization, WHO/UNICEF/WORLDBANK
- www.cdc.gov

instrumentation, and system technical data into the Construction Completion Records used during IQ/OQ.

Together, these approaches resulted in an accelerated transfer of system ownership from Construction to Commissioning to Qualification to Operations.

Conclusion

Despite formidable odds, the VBF project team was able to meet Merck's goal of providing Varicella to more patients. Through an integration-focused design, build, deliver approach, the team completed the project in record time (Charter to OQ completion in roughly 24 months – 40% faster than industry benchmarks) with a savings of $43,000,000. Millions of patients will now be able to receive preventative vaccinations for chickenpox and shingles from a world class facility that is part of Merck's global supply chain.

Facility of the Year Awards

Sponsored by ISPE, INTERPHEX and Pharmaceutical Processing magazine, the Facility of the Year Awards (FOYA) program recognizes state-of-the-art pharmaceutical manufacturing projects that utilize new and innovative technologies to enhance the delivery of a quality project, as well as reduce the cost of producing high-quality medicines. Now in its ninth year, the awards program effectively spotlights the accomplishments, shared commitment, and dedication of individuals in companies worldwide to innovate and advance pharmaceutical manufacturing technology for the benefit of patients.

2012 Facility of the Year

Merck's Vaccine Bulk Manufacturing Facility (VBF) Program of Projects, category winner for Facility Integration, was selected as the Overall Winner of the 2012 Facility of the Year Awards among five other Category Winners in 2012. A sixth facility was

selected to receive a Special Recognition. The winning companies and respective award categories are:

- Chiesi Farmaceutici S.p.A, winner of the Facility of the Year Award for Sustainability for its Research and Development Centre in Parma, Italy
- Eisai Pharmatechnology & Manufacturing Pvt. Ltd., winner of the Facility of the Year Award for Project Execution for its Eisai Knowledge Centre in Visakhapatnam, Andhra Pradesh, India
- Rentschler Biotechnologie GmbH, winner of the Facility of the Year Award for Equipment Innovation for its REX III project in Laupheim, Germany
- Roche Diagnostics GmbH, winner of the Facility of the Year Award for Operational Excellence for its TP Expand project in Penzberg, Germany
- National Institute for Bioprocessing Research and Training (NIBRT), winner of the Facility of the Year Award Special Recognition for Novel Collaboration for its New Greenfield facility in Dublin, Ireland

More information on the Facility of the Year Awards program can be found at www.FacilityoftheYear.org.

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Why Conduct Pilot Studies for Agitated Gas-Liquid Mass Transfer?

by Gregory T. Benz

This article presents the rationale for conducting detailed mass transfer correlation studies in aerobic fermenters, in order to minimize power consumption in full scale design and maximize the chance of having correctly designed equipment.

Introduction

In an agitated, aerated bioreactor, one of the significant costs is electrical power. Several years ago,[2] a study described that the power used for agitated, gas-liquid mass transfer consisted mainly of two sources: agitator power and compressor power. For the specific case of an aerated bioreactor, it was shown that the sum of these two power sources goes through a minimum, as a function of airflow, bounded by stoichiometry at the low end of airflow and by excessive liquid entrainment at the high end of airflow. This concept is illustrated in Figure 1.

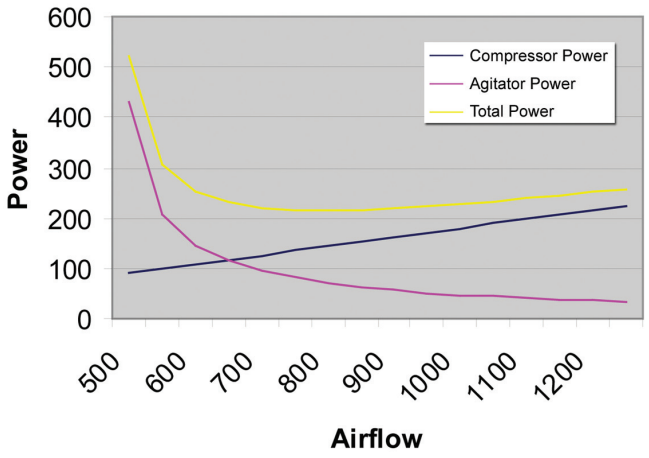

Figure 1. Power minimization curves.

Such a curve depends on having an accurate relationship for calculating the mass transfer coefficient and there are sources that explain how to design a pilot program to empirically create such a relationship. The purpose of this article is to illustrate vividly the possible error in published correlations compared to real broth data, and thereby emphasize the importance of experimental work to develop process-specific correlations.

Background

We will use an aerobic bioreactor as an illustration of concept for this article. For such a reactor, mass transfer may conceptually be written in the form:

$$OTR = k_La^* \text{ (driving force)} \quad (1)$$

In the above correlation, kL is the liquid film coefficient, and has units of length/time, e.g., M/s. "a" is interfacial area/volume, and has units of 1/length, e.g., 1/M. Thus, k_La has units of 1/time, e.g., s^{-1}. Driving force has units of mass or moles/volume, e.g., mmol/l or mg/l.

For a small vessel (< 1000l, for example), the driving force is simply the difference between the actual mean Dissolved Oxygen (DO) concentration and the mean saturation value, or (C_{sat} – C). (The value of Csat depends on the partial pressure of gas at the location in question, as well as the temperature.) For a larger vessel, it is best to use a log mean driving force:

$$\text{log mean driving force} = \frac{(C_{sat} - C)_{in} - (C_{sat} - C)_{out}}{\ln ((C_{sat} - C)_{in} / (C_{sat} - C)_{out})} \quad (2)$$

Thus, if driving force and k_La are known, the mass transfer rate is easily determined. But how is this k_La calculated? Though many different forms of correlation have been used in the literature, the most common form is:

$$k_La = A(P/V)^b(U_s)^c \quad (3)$$

The constants, A, B and C, must be experimentally determined for the specific gas-liquid system in question. They may depend on the actual magnitudes of P/V and U_s, and possibly on impeller type and scale of equipment, as well as the chemical composition and physical properties of the gas and liquid. For these reasons, it is important to try not to extrapolate the correlation beyond the range over which it was developed. The dimensions of "A" depend on the units used; it is not a dimensionless number.

Several such correlations have been published in the literature. The works of many others were summarized[4] by dividing their data into coalescing systems (essentially tap or distilled water) and non-coalescing systems (essentially water with high ionic strength, as would be expected of fermenters with a nutrient solution as the broth.) Later, an "average" correlation for an air-water system was published.[1] These authors note that such correlations are generally no more than ± 30% accurate.

This author has worked with various clients over the years to design experimental programs and interpret the results for specific broths. A couple of these will be used in this article, called simply broth 1 and broth 2. These two broths differ markedly from the published correlations, as can be seen in Table A.

Full Scale Example

To illustrate the consequences of different kLa correlations, the total power as a function of airflow was calculated using the methods[2] for the following specific production bioreactor data and assumptions:

Mass Transfer Correlation Constants	A	B	C
Bakker (1)	0.946	0.6	0.6
Coalescing (4)	0.41	0.4	0.5
Non-coalescing (4)	0.25	0.7	0.2
Broth 1	0.67	0.55	0.6
Broth 2	3.73	0.542	0.741

Table A. Typical constants used in mass transfer correlations.

- Tank diameter : 5 M
- Liquid volume: 229000 l
- Ungassed liquid level: 12 M
- Temperature: 37°C
- Feed gas: air, at 21% oxygen
- Csat at 21% oxygen, 1 atmosphere: 7.2 mg/l
- DO at bottom of vessel: 2 mg/l
- DO at top of vessel: 1 mg/l
- Backpressure: 0.3 bar
- Barometric pressure: 1 atm or 760 torr
- Moles of CO_2 respired per mole of oxygen consumed: 0.95
- Liquid density: 1000 g/l
- Total gas line pressure losses: 1.5 bar
- Compressor efficiency: 70%
- Agitator mechanical efficiency: 95%
- Design OTR: 150 mmol-l-h

The total power (agitator plus compressor) has been plotted in Figure 2 as a function of airflow in a series of curves representing each of the k_La correlations in Table A.

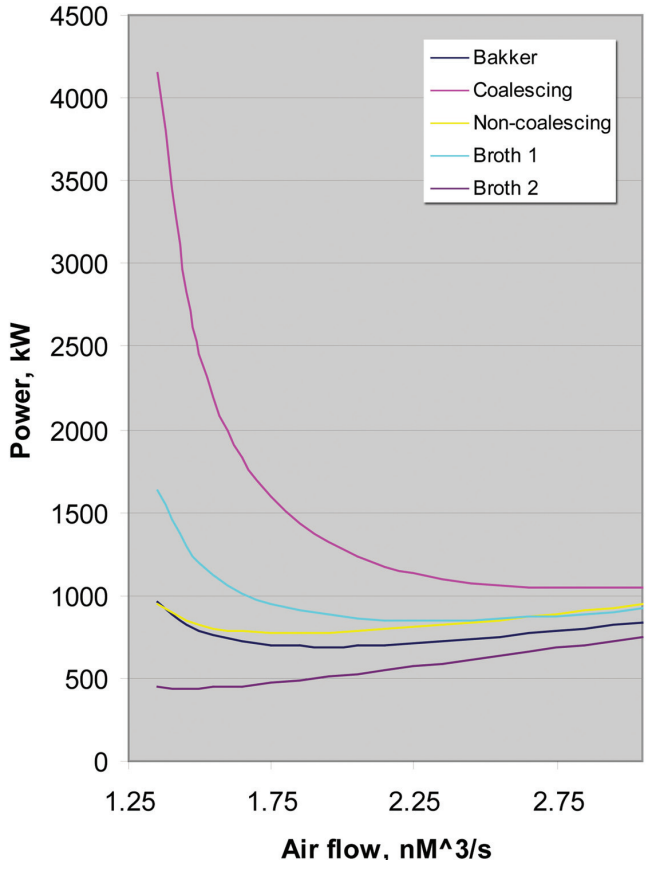

Figure 2. The total power (agitator plus compressor).

Discussion of Results

As can be seen, even the published correlations can differ from each other by a factor of 3 or more. Actual broths can deviate significantly from each other as well as published correlations. One could easily be seriously in error if the wrong correlation is used for design. In one direction, the wrong correlation can waste money by installing massively oversized equipment and using excessive power. An error in the other direction may result in lower product yield, lower product concentration, or even lower production capacity than the plant design calls for.

> *"Actual broths can deviate significantly from each other as well as published correlations.*

Looking Forward

Maybe someday there will be a universal k_La correlation which takes account all chemical and physical properties and is valid for all impeller types, covers all possible ranges of variables and includes all effects of scale. Until then, it is highly advisable to do the "wet" testing necessary to develop broth-specific correlations that lead to accurate design while minimizing total power costs. The present worth of electrical power costs can be $1,000 to $3,000 per kilowatt. Thus, the difference in power costs for a typical production fermenter can be hundreds of thousands of dollars depending on the correlation used. The exception of course, is for processes that produce such valuable products that massively oversizing equipment is a reasonable option.

Nomenclature

A	Correlation constant; units depend on correlation units.
a	Gas-liquid interfacial area/volume, 1/M
b	correlation exponent (dimensionless)
C	Dissolved oxygen concentration, mass or moles/volume (e.g., mg/l)
C_{sat}	Dissolved oxygen concentration at saturation (mg/l)
c	Correlation exponent (dimensionless)
DO	Dissolved oxygen concentration, general term (mg/l)
k_La	Overall mass transfer coefficient, 1/time (1/s)
k_L	Liquid film coefficient, M/s
OTR	Oxygen Transfer Rate, mass or moles per volume-time), e.g. mg/l-hr.
P	Agitator power, W
P/V	Specific Power: agitator invested power/(mass or volume) of liquid (e.g., W/l)
U_s	Superficial Gas Velocity, distance/time (M/s)
V	Liquid volume, l
VVM	Volume of gas/volume of liquid/minute at standard conditions (min-1)
Z	Liquid level within tank, M

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About the Author

Gregory T. Benz is President of Benz Technology International, Inc. He received his BSChE from the University of Cincinnati in 1976, and has taken a course on fermentation biotechnology from the Center for Professional Advancement. A registered Professional Engineer in Ohio, he has more than 35 years of experience in the design of agitation systems. Currently, his company does general mixing consultation, including pilot plant protocol, equipment specification, and bid evaluation. Current activity includes several cellulosic ethanol, single-cell protein, and biomass projects. Benz also teaches courses on agitation with CEU/PDH credits. He is a member of AIChE, ISPE, SIM, and the American Chamber of Commerce in Shanghai. He is a Course Director for Aurora Analytics (www.aurora-analytics.com), currently teaching two courses on fluid agitation: one for bio/pharmaceutical, the other for biofuels. He is a registered expert with Intota (www.Intota.com). He can be contacted by telephone: +1-937-289-4504 or email: benztech@mindspring.com.

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Facility of the Future: Next Generation Biomanufacturing Forum

Part I: "Why We Cannot Stay Here" – The Challenges, Risks, and Business Drivers for Changing the Paradigm

by Mark Witcher, PhD, Ruben Carbonell, PhD, Jeff Odum, CPIP, Peter Bigelow, Patricia Lewis, and Michael Zivitz

This article is the first of a three-part series focused on defining the facility of the future required for manufacturing biopharmaceuticals in the 21st Century.

Introduction

This article is the first of a three-part series focused on defining the Facility of the Future (FoF) required for manufacturing biopharmaceuticals in the 21st Century. These articles are the result of discussions and presentations made by experienced industry and academic leaders from companies partially listed below at the "NextGen Facility Forum" held at North Carolina State University's Biomanufacturing Training and Education Center (BTEC) on 31 January 2012, sponsored by BTEC and IPS. The goal of the forum was to identify and clearly state all the challenges that biopharmaceutical manufacturing will face, and to begin to identify solutions to the biopharmaceutical industry's outdated manufacturing facilities that have difficulty adapting to the changing manufacturing requirements. Some of these changes include efficiently running smaller scale processes utilizing single use, disposable systems among others. The three articles will cover the topics discussed at the forum to make the Facility of Future capable of addressing all the issues that biopharmaceutical manufacturing will face in the next century.

The forum was designed around three breakout sessions covering the following questions:

1. What are the major process and design needs that are not being met by existing technologies?
2. What are the key process technologies that are important in transitioning the industry to these smaller, greener, more flexible facilities?
3. What are the regulatory and validation policies that will help cut costs and reduce time to market for products made in the new biopharmaceutical facilities of the future?

Between the breakout sessions, the following four presentations were made:

- "The Facility of the Future's Importance to Industry" by Peter Bigelow – Former President, North American Operations, Patheon, Inc.
- "The Role of Innovation in Future Facility Development" by Michael Kowolenko, PhD. – Industrial Fellow, CIMS, NC State University
- "The Role of Enabling Technologies" by Rubin Carbonell, PhD – Director, BTEC Programs, BTEC
- "Next Generation Manufacturing" by Mark F. Witcher, PhD – Principal Consultant, IPS

The forum's presentations, breakout discussions, and large

group conversations focused on the current issues facing the biopharmaceutical industry as companies move into the decision-making process for implementation of new technologies and facility design approaches. General agreement was reached that facility design concepts and technology used in current biopharmaceutical manufacturing facilities need to change considerably if they are to meet the manufacturing challenges of the future. This concern was manifested in a large number of discussion points raised in the various sessions, including, but not limited to the following themes:

- **Business Drivers** – impact of property, plant, and equipment on the bottom line; reduced depreciation targets across asset base.
- **Capital Drivers** – limited future capital availability, need to improve cash flow objectives to achieve lower overall cost of new assets.
- **Asset Utilization** – provide higher utilization of manufacturing assets.
- **Timelines** – reduce construction timelines to defer capital spending and enable emerging market development of new assets.

General consensus was reached that the facilities currently being constructed are too expensive and do not have the flexibility to respond to challenges created by future biopharmaceutical products, processes, and markets.

Manufacturing capability is a critical function for the development, launching, and supply of the biopharmaceutical market with high quality therapeutics. The first step to reaching an understanding of the FoF is to understand the challenges presented by biopharmaceutical manufacturing. For the sake of discussion, the challenges are divided into business drivers and uncertainty. After the challenges are discussed, the resulting business risks associated with manufacturing will be defined.

Challenge #1: Managing the Manufacturing Business Drivers

Like all manufacturing enterprises, biopharmaceutical manufacturing has basic business drivers that define the success of the enterprise as an efficient, cost effective contributor to the overall business. From the discussions, the basic drivers for any biopharmaceutical manufacturing facilities are shown in Figure 1.

As seen in Figure 1, the drivers can be divided into two categories. The first is patient safety and efficacy and are imperative for a successful product. The second category is basic business drivers. All the drivers rarely stand alone, and as such, must be balanced against each other to maximize the effectiveness of the manufacturing operation in meeting overall business goals. The critical-to-success factors associated with the unique drivers of each venture will result in different drivers being prioritized over others.

Product Quality

Product Quality is a given and as such, manufacturing operations must be designed and operated to reliably provide the patient population with a high quality product. In the context of this discussion, product quality is defined as the overall value to the patient in terms of the product's attributes of safety, potency, purity, and efficacy combined with other patient requirements, such as availability and cost. When all these patient-driven needs are met, product demand is typically high and the business enterprise is successful.

Excellence and Compliance

A critical driver to achieving the first driver is to maintain a facility that uses operational excellence to remain in compliance with appropriate regulatory guidelines. The regulatory guidelines provide the basis for current Good Manufacturing Practices (cGMPs) and process validation which define standards for regulatory inspections and product submissions for approval. In biopharmaceutical manufacturing in particular, meeting all the other business drivers requires manufacturing excellence which is a superset of requirements necessary to be compliant with regulatory guidelines. However, a complete knowledge, understanding, and implementation of all the applicable guidelines are required to assure compliance at all times.

Operating Cost

In terms of biopharmaceutical manufacturing facilities, the overall cost of manufacturing a product can be viewed as a combination of operating and capital costs. With the current cost pressures on the industry as a whole, understanding and controlling both of these costs is critical.

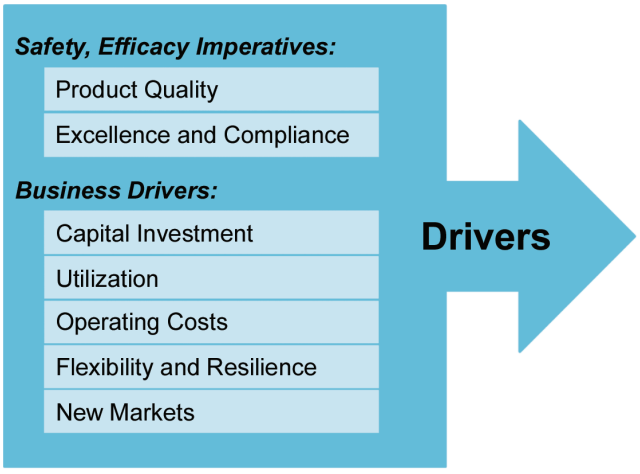

Figure 1. The business drivers can be divided into patient safety and efficacy imperatives, and business drivers associated with building and operating the manufacturing enterprise.

Manufacturing operations always look to control operating costs associated with raw materials, personnel, etc., by incorporating new technologies and optimizing the value provided by each cost component. Significant effort is being placed in advancing process technologies to increase productivity and product quality from both upstream and downstream processes that decrease operating costs and improve process performance. Single Use (SU) equipment and components is a notable example of a technology which can be used to significantly reduce start-up and operating costs in some applications.

Facility Utilization

High utilization rates almost always translate into cost effective facilities which provide high value to the enterprise. The goal is to build manufacturing facilities that are sized properly and have the characteristics and capabilities that allow them to run at a high production rate to achieve the business' objectives. Facilities that run at high utilization rates without being overloaded also tend to produce high quality products and thus are more likely to achieve the first business driver of satisfying the patient's needs.

Capital Investment

Another business cost driver is to minimize the resource investment required to develop and supply the market. Capital investment is a major component of the business resources required to bring a product from research through to the market, and to reliably supply the market with product. Deploying and operating new assets not only requires the commitment of capital, it also requires significant investment in resources that are often a rate limiting step in asset realization. As such, capital is a major contributor to the total resources the business must provide to bring a product from research to commercial supply. Assets with faster implementation schedules allow for deferral of resources, spending, and an improved cash flow.

Flexibility/Resilience

In the biopharmaceutical industry, flexibility can be a key enabler to improved facility utilization. If a manufacturing facility is flexible, with the capability to quickly and efficiently supply different multiproduct manufacturing requirements, it is far more likely to have a high utilization rate because it can handle a wide variety of the enterprise's manufacturing requirements. Of equal importance is that a flexible facility can support an emerging product pipeline where individual products may have various probabilities of success. Designing facilities with this level of flexibility protects companies from owning capital assets that require significant capital to reconfigure in order to support new products. Thus, a facility that can handle multiple phases of manufacturing for multiple products employing a variety of different processes is more likely to have a high utilization rate. Resilience is a variant of flexibility. In biopharmaceuticals, the facility must be capable of quickly and efficiently adapting to different multiproduct manufacturing requirements despite process problems and changing product demand.

New Markets

Enabling new markets is a key business driver as the pharmaceutical industry looks to meet significant, unmet medical needs while generating new sources of revenue. Many countries require local manufacturing for market access. The result is the need to configure future facilities to be rapidly and efficiently deployable to the emerging markets by a focus on optimizing the combination of capital costs, timelines, regulatory considerations, operational drivers, and the design of the process. The emergence of biosimilars will present a wide variety of opportunities and challenges.

A common theme for all of these drivers is the influence of new technology. New technology can influence cost by allowing lower cost capital solutions through smaller facilities and lower cost equipment, while also lowering operating costs with improved process performance and better utilization of raw materials, personnel, etc. New technology also can enable flexibility and higher utilization facilities. Significant effort is being placed in advancing process technologies to increase productivity and product quality from both upstream and downstream process.

Challenge #2: Dealing with Uncertainty

With the business drivers defined, the issue becomes one of managing these drivers in the context of the uncertainty intrinsic to the biopharmaceutical industry. These uncertainties translate into significant risks to the business drivers. The discussion continues by defining the uncertainty inherent in the biopharmaceutical industry and the impact of that uncertainty on the manufacturing facilities. This uncertainty can be grouped into six categories (product, process, timeline, capacity, regulatory, and location) - *Figure 2*.

These six uncertainty elements were identified as the sources of risk of either having expensive excess or unused capacity; or failing to provide the necessary high quality material in a timely manner to support product approval, or to support commercial sales. These risks ultimately result in high Cost of Goods (COG) and/or a significant loss of sales revenue.

Product

Product uncertainty comes from two possible negative clinical testing outcomes. If the product is shown to be ineffective, or is associated with significant adverse reactions, the product fails and the established manufacturing capacity is not needed. In addition, there is always a possibility that an adverse product profile may be identified after commercialization, which leaves the manufacturing facility no longer

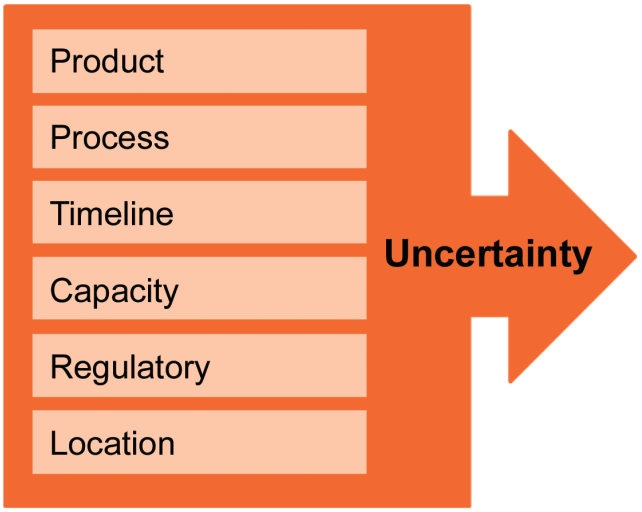

Figure 2. Business uncertainties associated with developing the product and the manufacturing enterprise.

required or severely underutilized. Clinical outcomes also can result in upside opportunities requiring additional capacity to serve the market.

Process

Another source of uncertainty is associated with the biopharmaceutical processes required to manufacture a complex, and sometimes very difficult to define and characterize protein product. The complex nature of the cell manufacturing systems and inherent complexity of the protein products provide the uncertainty of whether an efficient, cost effective process can be developed in a timely fashion to reliably provide sufficient amounts of product from a commercially viable large scale manufacturing process. Complex processes also introduce the possibility of operator errors and equipment failures that increase costs and delay production. Increased levels of training, automation, and sophisticated equipment validation and maintenance aid in decreasing the possibility of production problems.

Timeline

All of the uncertainties listed impact the timeline of building manufacturing capacity for all phases of the product development effort. The timeline element is broken out to reflect its significant overall contribution to managing the product development and commercialization effort.

Capacity

There is uncertainty in the ability to provide sufficient capacity to support product development and to supply preclinical, clinical, and commercial material. This includes uncertainty in the timing of establishing the required manufacturing capacity. Manufacturing capacity, even on the clinical scale, can be costly and time consuming to create. Critical milestone decisions and resource commitments must be made despite all the other uncertainties that provide the capacity to support the approval and launch timelines. Keeping manufacturing off of the critical path to product launch and market expansion requires significant and timely investments in development and manufacturing assets. New technologies and FoF concepts can help deliver accelerated schedules with simpler facilities and shorter lead time process systems that can provide plug-in installation and defer the need to make these capital investments.

Regulatory

Uncertainty also surrounds the regulatory approval process. Some regulatory uncertainty is associated with the product and how it is tested in the clinical setting. These issues are related and interactive with the other uncertainties described above. Regulatory uncertainty exists with establishing a manufacturing facility and operation which are compliant with regulatory guidelines. Differences in interpretation of GMP guidelines can lead to confusion and remains a distraction for many companies. In addition, some companies continue to struggle with on-going regulatory initiatives, such as PAT, QbD, design space, and process validation, particularly as defined in FDA's 2011 Process Validation Guidance. This uncertainty often results in overly conservative approaches with excessive costs and delays in development and manufacturing capacity creation.

Location

Future facility locations in emerging markets will be a key area of future uncertainty. Enabling the rapid global deployment of biopharmaceutical processes will be severely limited by today's facility and process designs. For example, high capacity, large volume stainless steel-based process trains are not ideally suited for deployment to emerging markets. The technology transfer of these existing technologies is very capital intensive and time consuming, and requires high risk upfront investments in both process and infrastructure. In addition, many emerging markets opportunities require lower capacities than traditional heavy stainless processes were envisioned to deliver.

While the individual risks associated with these uncertainties can be mitigated, the cumulative impact of these six areas of uncertainty results in significant overall risks with respect to establishing and operating the required biopharmaceutical manufacturing capacity.

Resulting Manufacturing Business Risks

Given the number of key business drivers and the large amount of uncertainty from many sources, the business risks associated with manufacturing are complex, interactive, and overlapping depending on the product and the patient

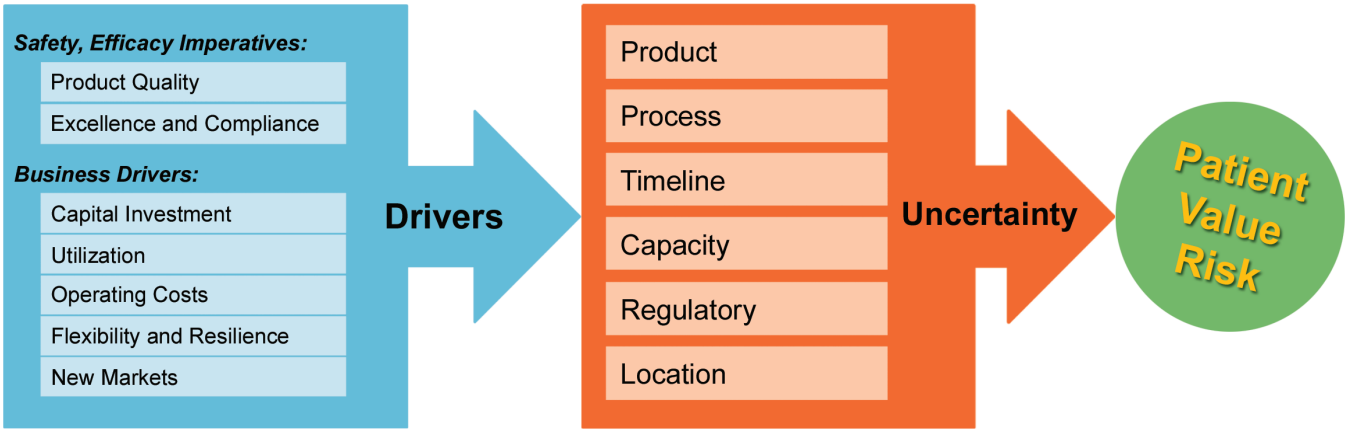

Figure 3. Patient value risks are primarily driven by patient safety, efficacy imperatives through the uncertainties; however, overall patient value risk in terms of cost and availability is also impacted by the business drivers and uncertainties shown.

indications being treated. For understanding, the risks can be lumped into risks associated with the value of the therapy to the patient (patient value risk) and the overall cost of delivering the therapy to the patients by the manufacturing enterprise (cost risk).

Patient value risks are associated with developing and supplying the therapeutic to the patient. The patient needs a timely, cost effective, reliable source of high quality product that is quickly and efficiently developed and delivered to the patient community. Figure 3 shows the qualitative relationship between the business drivers, uncertainty elements, and the overall risk to the value of the therapy to the patient. Failure of any of these relationships decreases the overall value of the therapy to the patients and thus decreases the opportunity revenue available to the business enterprise.

Cost risks are associated with the cost of supplying the therapy to the patients or Cost of Goods (COG). These costs are required to develop and launch the product as well as to provide long term supply of the product to the market place. The relative relationship between the same business drivers and uncertainties are shown in Figure 4. The capital investment required to build the facilities is a contributor to the COG throughout the product lifecycle from development through commercial supply. Anywhere along this lifecycle, a facility that is underutilized greatly increases costs while an undersized facility causes significant losses in potential revenue from failing to supply the patient population. Likewise, the manufacturing capacity needs to be available when the development and product launch timelines require it or the patient is underserved due to delayed availability of the product. In addition, inefficient or unreliable operation of the facility increases COGs through increased operating costs. Facilities of the future that look to new technology solutions also may enable a key industry transition from fixed to variable cost structures that can flex with demand.

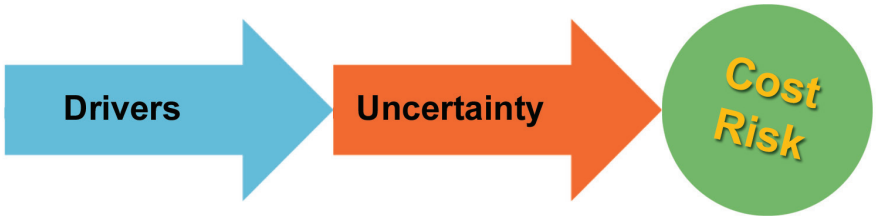

Figure 4. Product cost risks are driven through the uncertainties by the various business drivers shown. The cost risks are also impacted by the safety, efficacy imperatives of delivering a safe and effective product.

Summary

Defining and understanding the business drivers, uncertainties, and risks associated with building and operating biomanufacturing facilities is a key first step in the development of future generation facilities. The biopharmaceutical industry of today is very different and more complex than the industry that was birthed around the batch process, stainless steel asset facility model four decades ago.

Success of future facility design must be measured in terms of utilization, flexibility, and efficiency while providing a platform that supports and facilitates the operational excellence required for reliably producing high quality product while meeting an ever-evolving set of regulatory compliance guidance. As the industry looks to make this transition from current state to the future model, new enabling technologies can provide manufacturing platforms that meet the goals of being flexible with low capital unit operations changeovers, efficient movement to new markets, and a scale-out approach with smaller increments of capacity from highly productive processes to meet lower demand markets.

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The next article in this series, "Tools for Change – Enabling Technologies and Regulatory Approaches," discusses methods and approaches for achieving the business driver goals in light of the uncertainties and risks.

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A Science-Based Approach to Selecting Air Filters

by Steve Devine, Sean O'Reilly, Andy Stillo, and Don Thornburg

This article provides an overview of science-based factors to consider when selecting HEPA filters.

Introduction

Understanding the Total Cost of Ownership (TCO) and the material compatibility of HEPA filters is essential for engineers and end users seeking to optimize filter selection for performance reliability and sustainability. In order to give the reader a basic understanding of how filters work, it is essential that the principles of filtration are clearly defined.

Air filters are physically simple, yet technically complicated devices. Whether particulate or gas phase filters, they rely on a complicated set of mechanisms to perform their function. In many cases, more than one of these mechanisms comes into play. Many new technologies have been employed in the effort to improve on the quality and performance of air filters, and in some cases to reduce their cost. The most notable areas where advancement has been pursued are reduction in pressure drop and elimination of biological contaminants in the filter media. It is important to consider whether applying new technologies to air filter products is necessary and functional. In many cases it is, in some cases, it isn't. Certain technologies, like ionic air cleaners, may generate by-products that may be harmful to the environment. There are four mechanical principles, and one manufacturing-induced enhancement of filtration by which particles are filtered from the air by air filter media. They include impaction, interception, diffusion, straining, and electrostatic attraction, which can temporarily enhance the particle collection efficiency of the applicable mechanical principle.

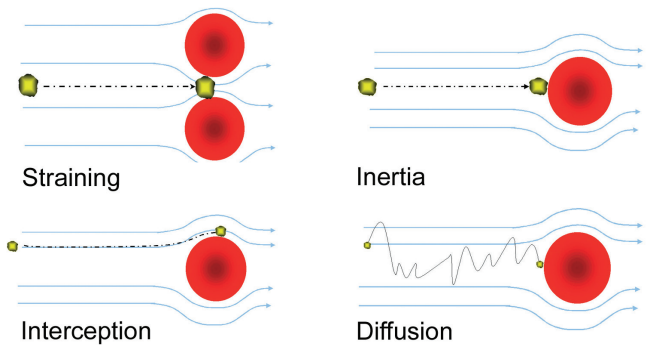

Figure 1. Principles of air filtration.

Each mechanism is responsible for filtration of particles in a certain size range:

Impaction: larger particles are filtered due to the impaction mechanism. Larger particles have higher mass and are harder to turn than smaller particles due to inertia. Because of this inertial effect, the particles continue to travel in a somewhat straight line even though the airstream is turning to move past the fiber. Once the particle comes in contact with the fiber, it becomes attached and is "filtered" from the airstream.

Interception: in order to be intercepted, a particle must come within a distance from a fiber of one radius of itself. Thus, the particle makes contact with the fiber and becomes attached. The interception mechanism can be contrasted with the impaction mechanism in that a particle which is intercepted is smaller and its inertia is not strong enough to cause the particle to continue in a straight line. Therefore, it follows the airstream until it comes in contact with a fiber.

Diffusion: is the most difficult air filtration mechanism to imagine or explain. Very small particles come in contact with fibers due to diffusive effects. The particles collide with air molecules and are "pushed around." This effect is called Brownian motion. Because of Brownian motion, small particles don't precisely follow the airstream, but instead "vibrate" or move erratically. This erratic movement increases the probability of the particles coming in contact with filter fibers.

Straining: is the air filtration mechanism in which the particle is larger in all dimensions than the distance between adjoining filter fibers. The particle gets stuck and can't make its way through the filter media. Straining is the mechanism of capture for large particles.

Electrostatic Attraction: filters utilizing large diameter fiber media (coarse fibers) may rely on electrostatic charges to increase their efficiency of fine particle removal. Large diameter fiber media is normally chosen due to low cost and resistance to airflow; however, these filters often lose their electrostatic charge over time because the particles captured on their surface occupy charged sites, neutralizing their electrostatic charge and the filters' real life efficiency.

A perfect air filter would operate at 100% efficiency on the target contaminants, require zero energy input, and last forever; however, no filter of this type has been invented. Filter efficiency, dust holding capacity, and differential pressure can be measured in many ways, and the performance of an air filter changes over time. The challenge imposed on air filters changes as the environment inside and outside of a building changes. Many air filter testing methods have been developed by various organizations for predicting the in-use performance of filters and for comparing the performance of air filters of different designs. It is important to understand the complexity of differentiating air filters. Many variables impact the results of a comparison study, some of which are obvious and some of which aren't. Most air filters will be in a system for months or even years; however, testing of these filters often occurs in a few minutes or hours. During its life, an air filter will see dozens or hundreds of environmental changes such as temperature, humidity, airflow velocity, and particle load. However, testing of filters often occurs in a controlled environment. Add to this the imperfect design of testing methods and the various motivations of the people developing test methods and you can conclude that you must fully understand how to interpret the results of any air filter test prior to using these results to make important decisions.

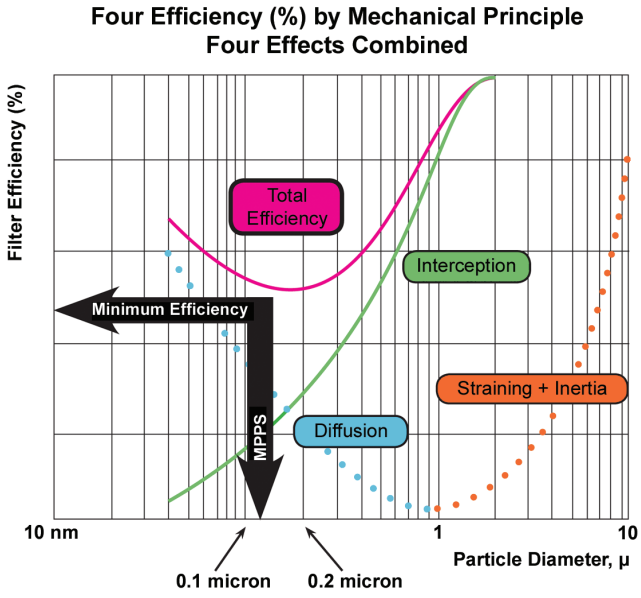

Figure 2. Air filtration mechanisms combined.

Organizations involved in setting filter standards and testing methods include:

- American Society of Heating, Refrigeration, and Air-Conditioning Engineers (ASHRAE)
- Institute of Environmental Sciences and Technology (IEST)
- Underwriters Laboratories (UL)
- Central European Norms (CEN)
- International Organization for Standardization (ISO)

Each of these organizations has an area of focus, but their standards and testing methods may overlap in some cases. Manufacturers have also developed several additional methods for predicting in-use performance, determining the performance of air filters in-use (in-situ), and comparing the performance of air filters of different designs.

The life science industry has additional challenges when it comes to selecting air filters. Sustainability cannot be ignored. Once the correct filter is selected for performance, the design should be optimized to maximize lifetime and reduce energy consumption, ideally based on real life data.[1] Compatibility of HEPA filter construction materials and how they perform or react with common cleaning agents, decontamination agents, and how test aerosols are applied will be explained in detail using a combination of laboratory and real life data. Membrane HEPA media (PTFE) is an interesting material with application possibilities, but also not without challenges; scientific study and test results will be reviewed with specific discussion on factory versus field testing. Specifying the correct filter efficiency and test procedure, and understanding aerosol generation techniques as well as HEPA filter repair limitations adds a level of complexity to the recipe for selecting air filters for the life science industry.

Using Life Cycle Cost (LCC) Analysis in the Air Filtration Industry

Using Life Cycle Cost (LCC) analysis as a tool to calculate the Total Cost of Ownership (TCO) and then selecting the air filter with the lowest TCO is an excellent method for determining the most cost-effective filtration solution to meet user needs. The current industry "standard" for calculating LCC was published by Eurovent in 1999[2] and specifically addressed the role of air filtration based upon life cycle cost. It outlined the calculation methods and formulas used when computing the LCC of an air filtration system. A proper LCC calculation allows owners to identify filtration solutions to help minimize system cleaning, reduce filter disposal costs, reduce labor costs, count the savings as "cost avoidance" with extended filter life, and utilize personnel for other activities.

There are different modeling software products available today. It's imperative when modeling a given application that the data be based upon science and real life testing, not hypothetical data or artificial loading. The use of real life testing is a very time consuming and costly way of evaluating filtration performance, but it provides the data needed to program modeling tools with the most accurate data and thus empowers end users with the confidence that the results are valid.

There are several key factors for selecting air filters to optimize energy consumption. The most important to remember is why the air filter was installed. The primary reason for the filter being installed was not to save money on energy. The air filter is there to remove particulate and contaminants from the air stream to protect the processes. If the filter can do that and use less energy, the air filter has added value.

We must always start with understanding what particle removal efficiency is required by the owner to protect the process, environment, or people. Unfortunately, there is a paradoxical relationship between energy savings and a filter's efficiency; generally, the higher the particle removal efficiency, the higher the energy consumption. Once the required particle removal efficiency requirement has been established, the filter selection can then be based upon additional criteria including:

1. Meeting this particle removal requirement throughout the service life
2. Optimizing the resistance to airflow for the air filter to reduce energy consumption
3. Minimizing the TCO of the air filter

Particle Removal Efficiency

The goal of LCC is to optimize the total cost of the filtration, while maintaining the minimum level of efficiency established by the owner or cognizant authorities. Unfortunately, a large number of commercially available filtration products use a filtration media that will show high particle removal efficiency in laboratory testing, but will decrease in efficiency during actual service. If these products were promoted at the lower performance level where they perform for most of their service life, there would be no confusion; however, they are typically marketed at the higher "test report" efficiency. Field data from real-life filter installations reveals some interesting facts about the relative performance of electrostatically charged media filters vs. non-charged media filters. Numerous studies have documented the real-life losses in filtration efficiency commonly encountered with charged media. Figure 3 shows the field performance data from the SINTEF[7] filter field test report showing the loss in efficiency over time for an ASHRAE 52.22[5] MERV 13 (F7 per EN-779[6]) filter. This study, in actual in-place testing exposed the drop in particle capture efficiency of synthetic or charged media.

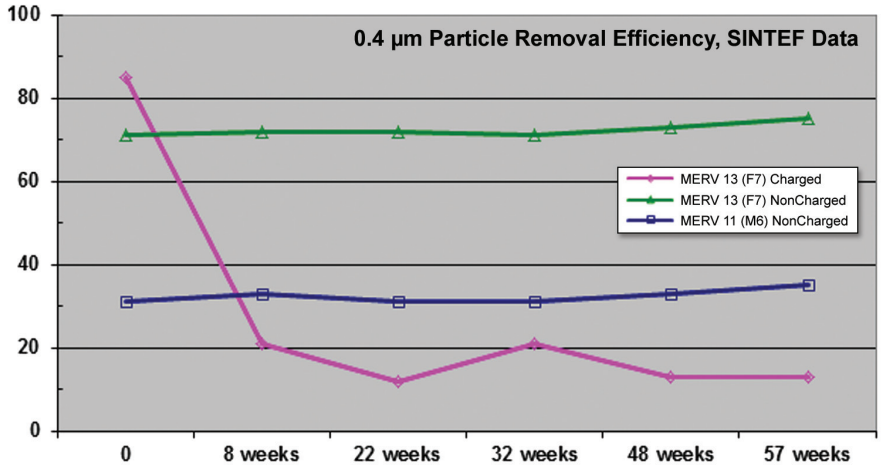

Figure 3. SINTEF air filter performance study.

Table A shows the relative comparison of the industry laboratory test methods for air filters and their efficiency nomenclature.

As shown in the data, the coarse fiber charged media of the MERV 13 (F7) filter really performs at a level below that of a MERV 11 (M6) filter. Thus, to properly run an LCC comparison on this charged filter, it should be compared to other MERV 11 (M6) filters. The MERV 13 (F7) non-charged filter performs according to expectations by maintaining a minimum efficiency very close to the initial efficiency throughout its life.

The point to be learned from this field data is that filters carrying the same laboratory test report designations may

behave very differently in real life. To obtain an "apples to apples" LCC analysis, filters of the same true efficiency must be compared. To better assist with this, ASHRAE 52.2[5]-2007B has an optional Appendix J test method that gives the user the conditioned MERV-A value designed to simulate the efficiency loss experienced by some filters in actual application. Likewise, EN-779[6] requires that the manufacturer report the discharged efficiency at 0.4 µm.

Resistance to Airflow

Once the actual particle removal efficiency is determined, the resistance to airflow for the product over the time in service must be evaluated. Some simple methods use initial pressure drop versus final pressure drop averaging, not a very scientific methodology and highly inaccurate. This laboratory testing is performed with synthetic dust of large particle size, not the much smaller sized contaminants typically found in the airstream. The purpose of that test is to expedite the filters' loading process so two filters of the same relative construction may be compared under controlled laboratory conditions. The test was never designed to simulate real filter life. Filters of an engineered design have long loading curves with 80% of their average pressure drop well below this averaging. The proper way to establish filter life for product comparison is to take advantage of accumulated real life data performance.

Using Life Cycle Cost and Total Cost of Ownership

For accurate LCC filter performance data, the best approach is to model current filter performance using typical operating conditions over a set time frame. Usually the owner has data relating to the filter change-out schedule, airflow rates, and airflow resistance values. When this information is input into LCC modeling software, average particle concentration loads may be determined. From there, how that specific system will perform, if energy efficient filtration is utilized, can be demonstrated. Once the owner accepts the proposed solution, the real fun begins. The new filters are installed and monitored for a period of time. Using standard energy measurement and verification practices, the performance data can be monitored and recorded to determine the associated cost avoidance or energy savings. This can then be included in the LCC calculations to evaluate the TCO for the air filtration systems. The LCC calculations include the cost of the filters, the energy cost, maintenance cost, disposal cost, and any associated cost to clean parts of the system. The TCO can add the additional costs to process orders, inventory materials, and any other costs associated with the purchase, installation, and operation of the system. The difference in TCO of replacing one filtration system with another system is the avoided cost for the owner and can be reported as a savings. Table A shows a typical LCC and TCO

TCO Elements	Current AHU[1]	Proposed Filter Solution	Comments	Calculation Component
Energy Cost	$25,935	$17,574	The main component of air filter cost is the ENERGY required to move air through the filter, often many times of the cost of the filter itself.	LCC
Filter Cost	$6,372	$3168	The cost of the initial filter and the replacement filters over the service time of the calculations.	LCC
Labor Cost	$792	$312	The labor cost to replace the used filters.	LCC
Waste Cost	$312	$72	The disposal costs of the used filters.	LCC
Mean Life Filter Efficiency (MLE)	71%	77%	The average calculated particle removal efficiency at 0.4 µm over the life of the filter.	TCO
Energy Cost Index (ECI)	7.65 USD/%	4.75 USD/%	The Energy Cost Index (ECI) is a method of relating the most important parameter of an air filter (particle removal efficiency) and the largest expense element; energy cost. The lower the ECI, the better the filter value.	TCO
CO_2 Impact	343,117 pounds	232,494 pounds	For this calculation the carbon footprint only considers energy usage. A more complete analysis would be required to get the full sustainability impact.	TCO
Landfill Impact	15.81 cubic yards	5.49 cubic yards	Landfill impact is another part of the sustainability equation for filter consideration. Fewer filter changes and/or lower volume (smaller size) filters can help here.	TCO
Period of Evaluation	3.0 years	3.0 years	Service time of this analysis.	LCC
Total Cost of Ownership	$33,411	$21,126	The New Filter solution will save this owner approximately $4,000 per year in total cost	TCO

[1] AHU – Air Handling Unit
[2] MLE – Filter efficiency at 0.4-micron, at the graph high point for number of particles in common airstreams, of a size that can enter the lungs and cause damage.

Table A. Sample output from air filtration total cost of ownership analysis.

data set for comparing two filtration systems of the same particle removal efficiency. Not all of the possible TCO costs and system impacts have been included. Particle removal efficiency, based upon the applications demands, should always be the driving force behind filter selection. Energy and sustainability factors when presented, allow facilities to apply total performance solutions.

Summary

Optimizing the filter selection is crucial to maximizing filter life and energy savings. Filter selection and optimization software allows facility operators to select filters based on scientific data. The result is verified savings in the hundreds of thousands of dollars per year on HVAC filters with little or no capital investment.

Factory vs. Field Testing of HEPA Filters

Cleanroom HEPA filters utilized in the life sciences require the end user to specify key parameters to ensure the proper installation and performance of their cleanroom. These parameters include, but are not limited to the following:

1. The size, including length, width, and maximum height, and frame configuration to properly fit the installation
2. A minimum global efficiency or maximum global penetration level at a specified particle size and flow-rate
3. A maximum local leakage penetration
4. A pressure drop target at a specified flow-rate
5. The required operational volume flow-rate or filter face velocity

The determination of the appropriate global filter efficiency specification is determined based on the final cleanroom cleanliness classification requirements. The traditional HEPA filter performance level specified within the life science industry has been:

- 99.99 efficiency vs. a mass median particle size of 0.3 µm (Type C per IEST-RP-CC001)
- 0.01% maximum local leakage penetration

The cleanroom HEPA filter, as installed, is typically required to meet a maximum leakage specification of 0.01%. This value is identical to the traditional filter factory leakage requirement. This has been cause for concern, as differences in equipment calibration and particle size could result in a filter failure in-situ after already passing factory test. Although this is a concern, it has not been identified as a significant issue, as border-line leaks are not very common.

Two common causes of in-situ failure of HEPA filters, not including physical/handling damage, originate in a difference in factory and field testing criteria. These are:

- Filter face velocity differences
- Test particle size differences

Any of these issues can result in the global filter penetration exceeding the 0.01% specification. This results in in-situ leak test failure of the filter after passing the factory test. The resulting failure typically appears as if the entire filter is leaking. This is known as "Excessive Non-Site Specific Penetration" (Bleed-Thru) and can be defined as: the measurement of background filter penetration exceeding the leakage specification during field certification.

Let's look at these common issues in more detail.

Filter Face Velocity

Filter manufacturers typically rate filters at a face velocity of 90-100 FPM in life science applications. The actual velocities in-situ can be significantly higher. Unfortunately, end user specifications do not typically indicate the maximum application velocity that the filter design may be applied. It is not unheard of to see filter face velocities from 120-150 FPM and even as high as 180 FPM. This upward shift in velocity has a dramatic negative impact on filter efficiency.

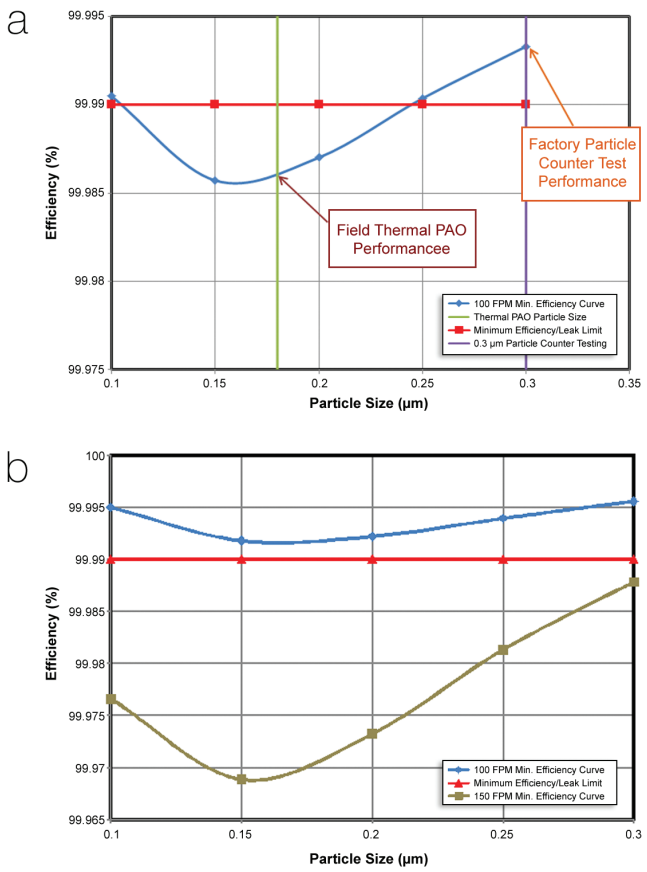

Figure 4. Typical cleanroom HEPA filter efficiency curves.

Therefore, a filter that passes efficiency and leak testing at 100 fpm in the factory may fail in-situ leak testing at a higher velocity. Figure 4b demonstrates this downward shift in efficiency, with increased velocity for a typical cleanroom HEPA filter.

Test Particle Size

Historically, life science facilities typically specified an IEST-RP-CC001[1] "Type C" or performance indicative of a "Type C" filter. The "Type C" requirements specify photometric efficiency testing using near mono-dispersed 0.3 micron diameter (mass median) thermal dioctly-phthalate (DOP) aerosol. Over the last 20 years, DOP testing has been discontinued in the field and by most filter manufactures due to potential health-related issues. It has been replaced with Poly Alpha Olefin (PAO). In this case, filter manufacturers are generating a polydispersed aerosol and using particle counters looking at 0.2-0.3 µm particles. In-situ, however, they are utilizing photometers. In Class A areas (fully filtered ceilings), field certifiers utilize portable thermal generators in order to achieve sufficient upstream concentrations. These generators produce an aerosol in a size range at or very close to a typical cleanroom filter's Most Penetrating Particle Size (MPPS). If a factory tested filter just meets the 99.99% @ 0.3 micron efficiency specification and is then tested with thermal aerosol in the field, it will likely exhibit "Excessive Non-Site Specific Penetration," since the in-situ efficiency will be lower when tested at or near the filter's MPPS. Figure 4a demonstrates this effect.

For those end users that utilize the traditional HEPA filter specification identified in the FDA sterile guide, the solution is to properly specify the filter. This requires that the maximum velocity be specified for the particular filter design. The other option would be to have different filter models for high velocity areas. This is typically frowned upon, as the end user prefers to stock or specify one model. It also requires that the filters' particle removal and leakage criteria be better specified. The end user will typically rely on using industry standards as a basis. The standards/practices utilized to specify cleanroom filters are IEST-RP-CC001[1] (HEPA and ULPA Filters), EN-1822[3] (high efficiency

Filter Class	Particle Size for Testing	Global Values		Local/Leak Values		
		Collection Efficiency (%)	Penetration (%)	Collection Efficiency (%)	Penetration (%)	Multiple of Global Efficiency (%)
E10		≥ 85	≤ 15	-	-	-
E11		≥ 95	≤ 5	-	-	-
E12		≥ 99.5	≤ 0.5	-	-	-
H13	MPPS[a]	≥ 99.95	≤ 0.05	≥ 99.75	≤ 0.25	5
H14	MPPS[a]	≥ 99.995	≤ 0.005	≥ 99.975	≤ 0.025	5
U15	MPPS[a]	≥ 99.9995	≤ 0.0005	≥ 99.9975	≤ 0.0025	5
U16	MPPS[a]	≥ 99.99995	≤ 0.00005	≥ 99.99975	≤ 0.00025	5
U17	MPPS[a]	≥ 99.999995	≤ 0.000005	≥ 99.9999	≤ 0.0001	20

[a] MPPS = Most Penetrating Particle Size

This European standard is based on particle counting methods that actually cover most needs for different applications. EN1822:2009 differs from its previous edition (EN1822:1998) by including the following: an alternative method for leakage testing of Group H filters with shapes other than panels; an alternative test method for using a solid, instead of a liquid, test aerosol; a method for testing and classifying of filters made out of membrane-type media; and a method for testing and classifying filters made out of synthetic fiber media. The main difference is related to the classification for the filter classes H10 – H12, which has now been changes to E10 – E12.

Table B. EN1822 classifications.

Filter Class (Group)	Particle Size for Testing	Global Values		Local/Leak Values		
		Collection Efficiency (%)	Penetration (%)	Collection Efficiency (%)	Penetration (%)	Multiple of Global Efficiency (%)
ISO 15 E	MPPS	≥ 95	≤ 5	-	-	-
ISO 20 E	MPPS	≥ 99	≤ 1	-	-	-
ISO 25 E	MPPS	≥ 99.5	≤ 0.5	-	-	-
ISO 30 E	MPPS	≥ 99.9	≤ 0.1	-	-	-
ISO 35 E	MPPS	≥ 99.95	≤ 0.05	≥ 99.75	≤ 0.25	5
ISO 40 E	MPPS	≥ 99.99	≤ 0.01	≥ 99.5	≤ 0.5	5
ISO 45 E	MPPS	≥ 99.995	≤ 0.005	≥ 99.975	≤ 0.025	5
ISO 50 E	MPPS	≥ 99.999	≤ 0.001	≥ 99.995	≤ 0.005	5
ISO 55 E	MPPS	≥ 99.9995	≤ 0.0005	≥ 99.9975	≤ 0.0025	5
ISO 60 E	MPPS	≥ 99.9999	≤ 0.0001	≥ 99.9995	≤ 0.0005	5
ISO 65 E	MPPS	≥ 99.99995	≤ 0.00005	≥ 99.99975	≤ 0.00025	5
ISO 70 E	MPPS	≥ 99.99999	≤ 0.00001	≥ 99.9999	≤ 0.0001	10
ISO 75 E	MPPS	≥ 99.999995	≤ 0.000005	≥ 99.9999	≤ 0.0001	20

ISO 29463-1:2011 establishes a classification of filters based on their performance, as determined in accordance with ISO 29463-3, ISO 29463-4 and ISO 29463-5. It also provides an overview of the test procedures, and specifies general requirements for assessing and marking the filters, as well as for documenting the test results. It is intended for use in conjunction with ISO 29463 2, ISO 29463 3, ISO 29463-4 and ISO 29463-5.

Table C. ISO 29463 classifications.

air filters (EPA, HEPA and ULPA)), and newly published ISO 29463[4] (high efficiency filters and filter media for removing particles from air). Tables B to D show the filter classifications contained within each of these standards/practices.

When considering the previous discussions concerning particle size and the in-situ leak requirements, HEPA filters specified using both EN1822[3] and ISO 29463[4] can result in field failure after passing factory testing when utilized in the life science industry. Both standards typically specify a leak value that is five times the minimum specified global efficiency. Selecting an appropriate filter that has a slightly higher minimum global efficiency than the field requirement results in the selection of an H14 filter according to EN1822[3] and an ISO 45 E filter according to ISO 29463.[4] Both of these filters have a global efficiency of 99.995% at the MPPS; however, the leakage criteria specified by both is 0.025% (5 times the minimum efficiency requirement). This value is 2.5 times the maximum 0.01% typical in-situ requirement. Again, as previously indicated, failure for pin-point leaks that are greater than 0.01%, but less than 0.025% are not very common. With that in mind, since both the EN1822[3] and ISO 29463[4] standards test at the MPPS, they would solve the issue of failure due to "Excessive Non-Site Specific Penetration." IEST-RP-CC001[1] has added a specific filter type for the life science industry. The IEST-RP-CC001[1] Type K filter also has a minimum global efficiency of 99.995% and maximum leakage criteria of 0.008% (1.8 times the minimum efficiency requirement). This is less than the 0.01% in-situ requirement, providing a safety factor that minimizes any possibility of rare borderline leaks causing failures in the field. This does not exclude the use of EN1822[3] or ISO 29463[4]; however, the end user needs to consider specifying a local leakage value to help ensure that filters that pass factory testing also will pass the in-situ testing.

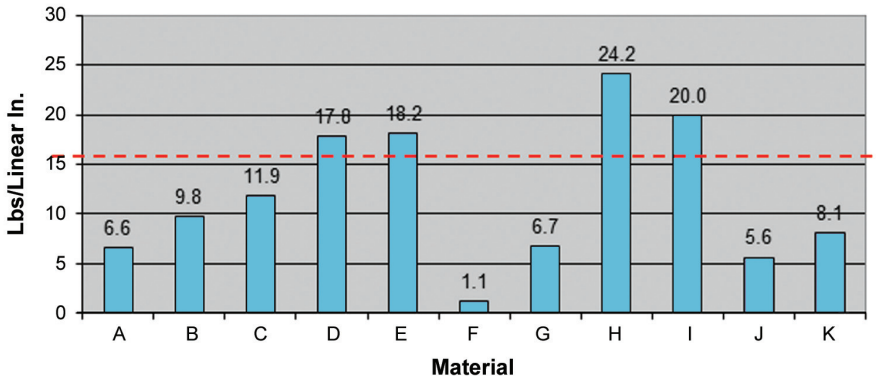

Figure 5. T-Peel results.

Filter Type	Particle Size for Testing	Global Values		Local Leak Values		
		Collection Efficiency (%)	Penetration (%)	Collection Efficiency (%)	Penetration (%)	Multiple of Global Efficiency (%)
A	0.3[a]	≥ 99.97	≤ 0.03			
B	0.3[a]	≥ 99.97	≤ 0.03	Two-Flow Leak Test		
E	0.3[a]	≥ 99.97	≤ 0.03	Two-Flow Leak Test		
H	0.1-0.2 or 0.2-0.3[b]	≥ 99.97	≤ 0.03			
I	0.1-0.2 or 0.2-0.3[b]	≥ 99.97	≤ 0.03	Two-Flow Leak Test		
C	0.3[a]	≥ 99.99	≤ 0.01	≥ 99.99	≤ 0.01	1
J	0.1-0.2 or 0.2-0.3[b]	≥ 99.99	≤ 0.01	≥ 99.99	≤ 0.01	1
K	0.1-0.2 or 0.2-0.3[b]	≥ 99.995	≤ 0.005	≥ 99.992	≤ 0.008	1.6
D	0.3[a]	≥ 99.999	≤ 0.001	≥ 99.99	≤ 0.005	5
F	0.1-0.2 or 0.2-0.3[b]	≥ 99.9995	≤ 0.0005	≥ 99.995	≤ 0.0025	5
G	0.1-0.2	≥ 99.9999	≤ 0.0001	≥ 99.999	≤ 0.001	10

[a] Mass median diameter particles (or with a count median diameter typically smaller than 0.2 µm as noted above).
[b] Use the particle size range that yields the lowest efficiency.

This Recommended Practice (RP), IEST-RP-CC001.5, covers basic provisions for HEPA (high efficiency particulate air) and ULPA (ultra-low penetration air) filter units as a basis for agreement between customers and suppliers.HEPA filters and ULPA filters that meet the requirements of this RP are suitable for use in clean air devices and cleanrooms that fall within the scope of ISO 14644 and for use in supply air and contaminated exhaust systems that require extremely high filter efficiency (99.97% or higher) for sub micrometer (µm) particles. This RP describes 11 levels of filter performance and six grades of filter construction. The customer's purchase order should specify the level of performance and grade of construction required. The customer should also specify the filter efficiency required if it is not covered by the performance levels specified in this RP.

Table D. IEST-RP-CC001.

Compatibility of Construction Materials for HEPA Filters

A variety of polymer materials are used to manufacture HEPA filters. The most common is the sealant or "potting compound" that forms the leak-free bond between the filter media pack and the filter frame. The material of choice for this application is polyurethane. Polyurethane sealant is comprised of two liquid components (a polyol resin, and a diisocyanate hardener) that when mixed, create a solid cross-linked rubber-like polymer. Since these materials will not melt when heated, they are called thermoset polymers.

The filter gasket system is made using polymer foams including neoprene and polyurethane or gels made from soft polyurethane or silicone. Often a thermo-

plastic "hot melt" material is used to control and maintain regular separation between the pleats in the filter pack. While polymer materials have been used for many years to provide adhesion and flexibility, understanding their compatibility with other agents and their limitations is critical to achieving long and trouble-free filter service. HEPA filter manufacturers should qualify the materials they use by testing, and test results should be shared with end users upon request.

Polyurethane Potting

The polyurethane potting compound is a high-performance material capable of maintaining flexibility and adhesion over a wide range of temperatures. It is 100% solid, meaning there are no liquid plasticizers that could exude to the surface or evaporate over time causing the material to shrink, become brittle or "dry out."

Before being approved for use in a filter, the polyurethane is fully characterized and undergoes 14 rigorous performance evaluation tests, including outgassing analysis, adhesion, temperature cycling, and accelerated aging. The polyurethane is checked carefully to ensure it does not contain known compounds that could interfere with cleanroom processes.

Gel

The filter gel seal is a two-component, lightly cross-linked material made of polysiloxane or polyurethane. Like the potting compound, gel materials also are fully characterized and undergo a battery of tests to ensure quality and fitness for use. In addition to physical property testing, such as hardness (penetration), both silicone and polyurethane gels are exposed to decontamination agents and cleaning agents. They are also exposed to common filter test aerosols like Poly Alpha Olefins (PAO) to ensure that the effect of these oils on the gel is understood and does not cause the gel to fail.

Silicone gels are generally considered robust and offer very good resistance to chemical attack, but not all gels are equal. Some gel systems contain significantly more free liquid material. In certain circumstances and over time, this liquid material may be forced out of the gel by a process that is not yet fully understood.

Generally speaking, silicone gels with greater than 30% free liquid are associated with field issues of "dripping gel" after years of installation. Recent investigations have determined the free liquid content of many commercially available grades of gel by Soxhlet extraction. Wide variability of free liquid content between different grades and suppliers. Extraction results correlate directly with "blot-plot" results, which express the migration rate of the unbound phase and with gel softness. The softer the gel, the higher the extractable content and the faster rate of migration.

While some believe there may be a link to PAO exposure, this has not been clearly demonstrated and has not been experimentally proven in the laboratory. In numerous experiments where gel has been exposed or immersed in an excess of PAO, liquefaction has not been observed. Measurements indicate that silicone gel can swell up to about 5% when immersed in PAO; however, no loss in gel integrity was observed.

Compatibility with Cleaning Agents

High Efficiency Particulate Absolute (HEPA) filters are widely used to provide clean air to facilities where microorganisms cannot be tolerated and to filter the air leaving laboratories where pathogens may be present. In these situations, facilities are routinely cleaned and decontaminated, and HEPA filters are often exposed to antimicrobial agents.

Summary Test Results	Supplier A		Supplier B	
	High Viscosity	Low Viscosity	High Viscosity	Low Viscosity
Characteristic Parameter				
Total Outgassing by TD-GC-MS at 50°C / 30 minutes (ppmw)	0.56	3.5	2.7	1.6
Trace Element Analysis by ICP-AES, ICP-FID (EPA 200.7, EPA 200.8) (mg/Kg) Total of 11 elements	2.33	2.83	6	4.15
Linear Shrinkage (ASTM D 2566) (%)	0.593	0.282	0.25	0.22
T-Peel (ASTM D 1876) (Lbs./Lin. Inch)	20	24.2	11	11.3
Lap Shear (ASTM D 3163; ASTM D 5868)	358.4	240.4	297.9	361.3
Hardness Shore A (ASTM D 2240)	90	96	89	92
Hardness Shore D (ASTM D 2240)	47	57	47	55
Weight loss (Cured Sample, 107°C, 7 days) (%)	0.177	0.282	0.211	0.787
Flame Retardancy (Time to self-extinguish) (Sec.)	1	1	2	2
Dry Aging (Observe for exudation) (Pass / Fail)	Pass	Pass	Pass	Pass
Wet Aging (Observe for reversion)	Pass	Pass	Pass	Pass
Deep pour crack resistance	Pass	Pass	Pass	Pass
Reaction Stability	Stable	Stable	Stable	Stable
Adhesion to Anodized Aluminum Frame	Pass	Pass	Pass	Pass
Final Evaluation	Pass	Pass	Pass	Pass

Table E. Sealant summary test results.

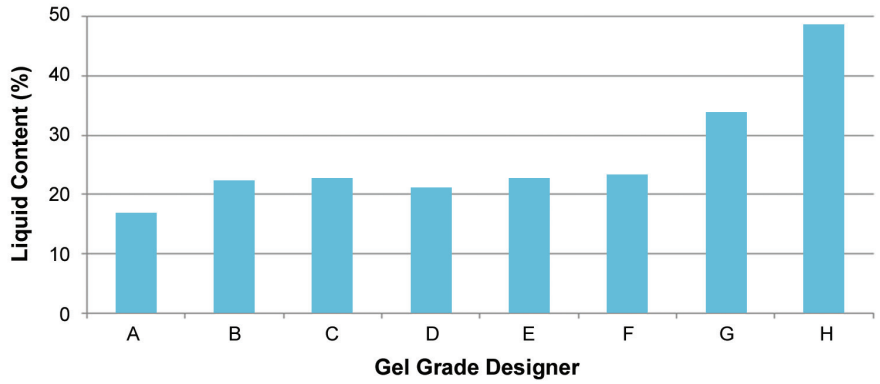

Figure 6. Liquid content of gel.

Recent research has considered the likely exposure of HEPA filters to decontamination agents. Laboratory testing and field experience indicates that the compatibility between HEPA filter materials and cleaning agents is good to excellent. Naturally, there is always interaction between decontamination agents and the materials they contact; indeed, that is how microorganisms are controlled. Under normal conditions, HEPA filters manufactured with qualified materials can withstand these effects without loss of performance.

In a recent year-long study where silicone gels were exposed to concentrated vapors generated by a variety of cleaning agents, the results indicated that these agents did not cause failure or "liquefaction" of silicone gel materials tested. The tests were conducted at elevated temperature to promote accelerated aging. Silicone gel was exposed to common antimicrobial cleaning agents, including one containing quaternary ammonium compounds, one containing sodium hypochlorite (bleach), and a third containing a blend of hydrogen peroxide and peracetic acid. There was no observed failure of the gel as defined by the formation of a liquid or oily substance on the surface; however, in cases following significant exposure, the blue pigment present in the gel sometimes faded and the gel became lighter in color or clear.

Exposure of silicone gel to very strong acids (like concentrated hydrochloric acid solution) or bases (like concentrated sodium hydroxide solution) should be avoided since these are strong enough to attack the partially ionic Si-O bonds in the polymer backbone.

Polyurethane gels are slightly less resistant to oxidative attack than silicone gels; however, polyurethane gels perform well to seal filter modules in cleanroom applications, and there may be other reasons to choose a polyurethane gel over a silicone gel.

Where silicone materials must be avoided due to their potential effect on a process or product downstream, polyurethane gels are often specified. A classic example is microelectronics cleanrooms, where trace molecular contamination by silicone can interfere with wafer etching processes and final product quality. Sometimes, polyurethane gel is selected because it is slightly less expensive. Prior experience with a silicone gel issue or process incompatibility may also persuade the user to select polyurethane gel. Polyurethane gel contains substantially more unbound liquid component in the form of plasticizer than silicone gel. Over a period of several years, a small amount of the plasticizer may evaporate from the gel surface, causing the formation of a light "skin." Some cutting of the gel by the knife edge and some micro-cracks form normally on the surface of the gel adjacent to the knife edge due to the tensile forces present.

Although the initial assumption upon removal of a filter that has been installed for some time is that there is a problem with the gel, in reality these phenomena are normal. Since these small cracks do not threaten to extend down to or completely around the tip of the knife edge, bypass of air around the filter media pack is prevented. However, it is best not to re-install a gel seal filter that shows extensive skinning or splits unless the gel is removed and replaced. Often the most cost-effective solution is to simply replace an old filter with a new one. The expected lifetime of a gel filter that has been removed is about five years. When undisturbed, gel filters often provide leak-free service well beyond five years.

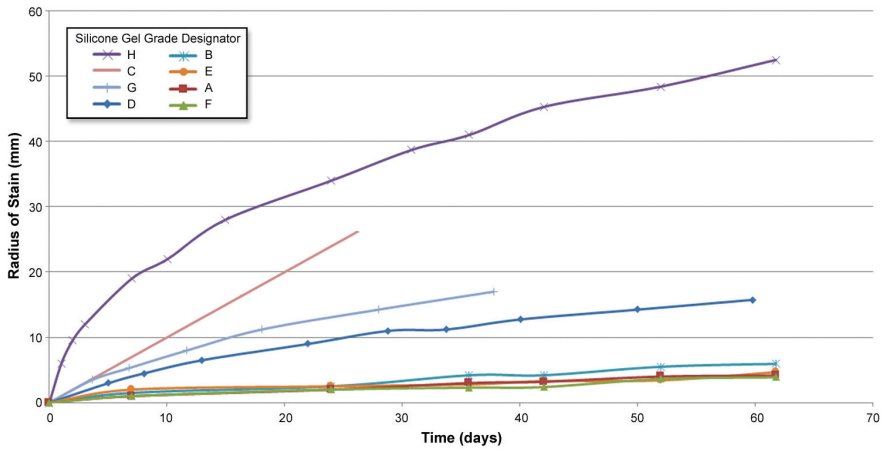

Figure 7. Gel plot blot at 30°C.

Compatibility with Space Decontamination Agents

In addition to cleaning agents, HEPA filter materials, including silicone gel, were exposed to common space decontamination agents, including formaldehyde, hydrogen peroxide vapor, and chlorine dioxide. The exposure routines simulated what would be expected during normal decontamination procedures during the 10-year service life of the filter.

Laboratory testing and field experience both indicate that when qualified materials are used to construct HEPA filters, they provide good to excellent chemical compatibility with formaldehyde, hydrogen peroxide, and chlorine dioxide when used for typical decontamination processes.

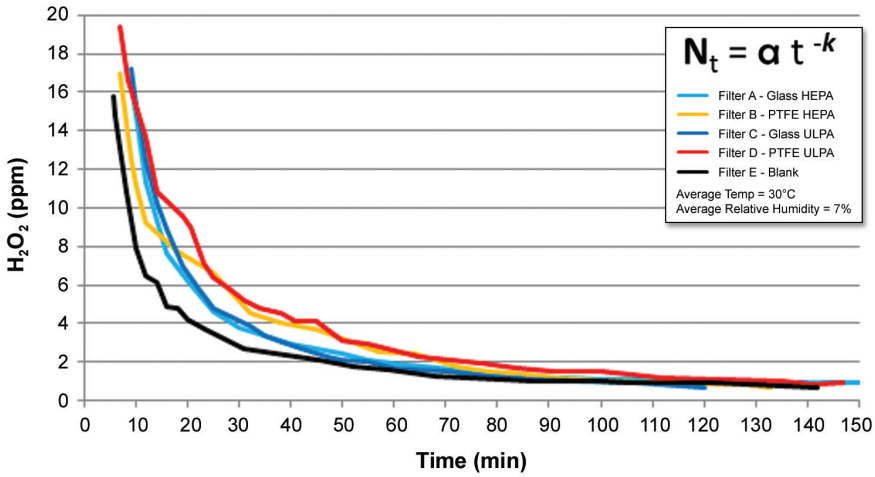

Figure 8. H_2O_2 desorption chart.

HEPA filters show excellent chemical compatibility with hydrogen peroxide under typical decontamination cycles. It is known that, over time, hydrogen peroxide adsorbs onto exposed surfaces; during aeration (or ventilation) it desorbs over time. Laboratory testing and field monitoring indicate that the presence of a HEPA filter in a system may delay the attainment of peak concentration levels downstream of the HEPA filter, due to the enormous surface area of the filtration media.

The HEPA filter also will capture droplets of aerosol in the air steam, if present. Hydrogen peroxide in the vapor phase will pass through the HEPA filter, and downstream concentrations will rise accordingly, approaching levels similar to upstream concentration levels once adsorption has occurred. After exposure, during the aeration phase, the opposite effect is observed. Downstream hydrogen peroxide levels will momentarily peak at the start of aeration due to rapid desorption from the filter media. Reduction in downstream concentration levels will initially lag that of the upstream level.

The overall aeration time may or may not be extended due to the presence of the HEPA filter, depending upon the type and area of other surfaces present in the system. Studies have shown that the use of expanded Polytetrafluoroethylene (PTFE) membrane filter media offered no advantages in terms of more rapid aeration compared to micro-fiberglass filter media when the aeration endpoint was <1 ppm H_2O_2. More rapid aeration can be achieved by using warm dry air for aeration.

HEPA filters also exhibited good compatibility with the chlorine dioxide process used for decontamination. It is recommended that welded stainless steel filter housings be treated by pickling prior to exposure to chlorine dioxide. HEPA filter potting compound made of polyurethane will show a characteristic yellowing following exposure to chlorine dioxide; however tests indicate no measurable change to the bulk properties and no loss in performance of the exposed polyurethane. Fraction negative decontamination studies using biological indicators inoculated with 106 spores of a target organism demonstrate the effectiveness of all three agents in decontamination of HEPA filters.

Membrane HEPA Filters in the Life Science Industry

In recent years, there has been a push by some media and filter manufacturers to promote PTFE media technology

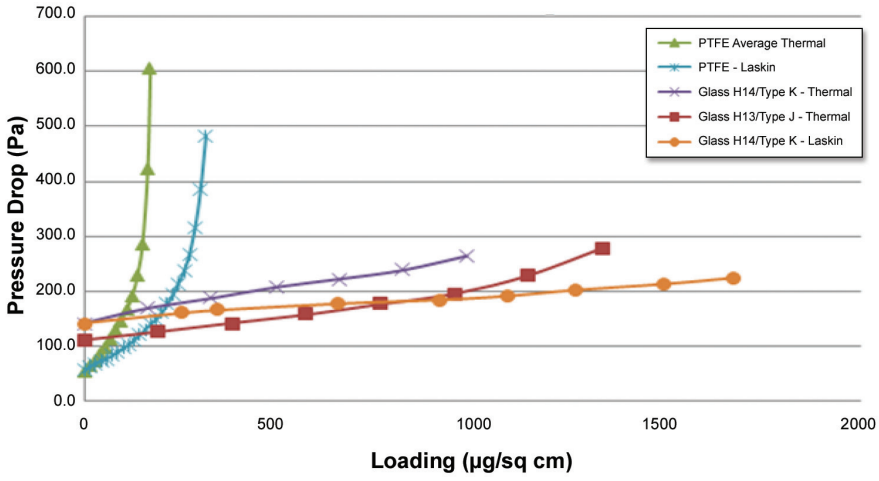

Figure 9. PTFE vs. glass grades loading curves.

to the life science industry. The application of this technology has been difficult due to its limited loading capacity. Although air supplied to these final filters is typically very clean, annual/biannual testing can substantially increase the pressure drop of these filters. Figure 9 demonstrates the substantial difference in loading characteristic between traditional micro-glass media and PTFE media filters. Both filters were loading with Laskin nozzle generated PAO aerosol.

As you can see in Figure 9, even though the initial pressure drop of the e-PTFE filter is lower than the micro-glass media filter, the rate of increase in pressure drop per unit mass of PAO loaded is substantially higher for the e-PTFE media.[8]

Over the last two years, there has been an attempt to implement e-PTFE filters in the life science industry. The basis of this implementation was testing these filters with very low concentrations of PAO aerosol along with the utilization of a discrete particle counter. This equates to a concentration < 0.1 µg/l as compared to > 10 µg/l when using a photometer.[3]

The microelectronics industry has tested PTFE filters with low concentration aerosol for over a decade. In this case, the aerosol used is microspheres (PSL microspheres) and the technology to generate this aerosol is well-established. The technology to generate ultra-low concentrations of PAO aerosol is not. This is evident based on the issues experienced.[3] In addition, in-situ testing of HEPA filters with discrete particle counters adds a substantial level of complexity compared to a photometer and PAO.

The "pros" are lower pressure drop and extreme durability. The "cons" are a cost approximately twice that of micro-glass fiber media (so even with lower pressure drop, the TCO is questionable), acceptable test methods, stable uniformity and airflow distribution, and readily available equipment to field test as outlined above. These obstacles, along with a reliable source of supply, remain a concern.

In summary, e-PTFE or membrane HEPA and ULPA filters have been manufactured since the 1990s. The industry needs to keep an open mind to applying this type of product. As technology continues to advance, discrete particle counter operation more closely simulates a photometer's operation, and reliable ultra-low concentration PAO aerosol generation equipment becomes available, e-PTFE media filters may have a place for specific applications within the life science industry.

Conclusion

There is a science to manufacturing, testing, supplying, and selecting air filters. Just like in the life science industry, raw material safety, material compatibility, longevity, reliability, consistency, and now more than ever, sustainability are absolute requirements if companies want to compete in this arena. Filters should be selected based on TCO for all applications, and buyers should ensure that air filter suppliers have the support, depth of knowledge, and experience necessary to deliver product consistently on a global basis.

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PHARMACEUTICAL ENGINEERING Interviews

George Gsell, President, MECO, Inc.

George V. Gsell is President of Mechanical Equipment Company (MECO), a leading manufacturer of engineered equipment for water purification. The firm has an 80-year history and a broad base of products for desalination and water purification. Gsell has more than 25 years of experience designing and constructing a variety of technologies for desalination and water purification, including vapor compression plants, multiple effect, waste heat and flash distillers, reverse osmosis plants, and enhanced membrane systems using micro- and ultrafiltration membranes. His experience includes applications throughout the world in the offshore oil and gas industry, onshore refining, biopharmaceutical applications, municipal water treatment, and state of the art military applications. He holds an MS in desalination technology from Glasgow University in Scotland and a degree in mechanical engineering from Tulane University. He is the author of several patents and papers in the industry related to desalination and water purification.

MECO is focused on water and water is a critical utility in the pharmaceutical industry. Can you tell us about the firm and its role in the industry?

MECO invented and patented the vapor compression process for the desalination of seawater in the early 1940s. Through the years, we have been developing technologies and systems for various industries such that these industries can meet their needs for fresh water. The vapor compression process is the most energy efficient method of distilling water and so the pharmaceutical industry began adopting the process for the production of water for injection in the early 1960s. In the 1970s, membrane processes such as reverse osmosis began to see widespread use. Today we manufacture a broad range of products that can deal with any water source for any industry. Our focus is primarily on customers who require a very high quality of product with the need for excellence in the execution of their project or delivery of their product.

Describe your professional development, your relationship with ISPE, and your role at MECO.

I have been designing and building various water purification technologies for close to 30 years. I have had the very good fortune to work with some of the pioneers in the business and today remain surrounded by a very talented team of people. I have had the opportunity to travel the world and get involved in a lot of water related problems and issues. As President of MECO, my role today is more focused on the long-term development of the business, process control, and administration. I engage our customer base directly on a routine basis and work on building a foundation for the learning and growth of our employees. My relationship with ISPE began about 20 years ago both as an educator and one who was being educated. I gave a few talks on water and in the process, learned more and

more each day about the pharmaceutical and biotech industries. Today we have a number of people engaged with ISPE and the document team for the ISPE Guide on Biopharmaceutical Process Development and Manufacturing. You will find us participating in various conferences, contributing to the ISPE Baseline® Guide on Water and Steam Systems Guide, and authoring technical papers. Through the years, we have patented several processes for the production of water to USP purified and water injection standards.

Was the ISPE Baseline® Guide on Water and Steam Systems or any other ISPE Guide used in any of these projects?

The ISPE Baseline® Guide on Water and Steam Systems has been a tremendous resource for us and the industry as a whole. Some of our people have been participants in the development of the Guide over many years. The Guide serves all of us (designers, contractors, vendors, regulatory officials) as a reference tool. We use the Guide continuously as a resource in designing and constructing systems, as well as educating the industry.

Water has captured everyone's attention today. Can you tell us why? Give us your perspective.

Freshwater is a limited resource. Severe weather patterns have impacted the hydrological cycle such that existing supplies are stressed. The world population is growing and with that growth comes not only the increased demand on freshwater sources, but also the contamination of existing supplies through industrialization. Right here in our home state of Texas, we built a multimillion gallon per day reverse osmosis plant to treat groundwater that had been contaminated by farm runoff posing a health hazard. Water is a resource we often take for granted, but if you look a little deeper, you will come to realize that industry consumes and wastes vast amounts of freshwater to deliver the goods and services we routinely use. The pharmaceutical industry is no exception.

MECO is building a new manufacturing facility here in the US that will serve the biopharmaceutical industry. Why here, why now, and what is special about this new facility?

Our principal manufacturing facility was located in New Orleans, LA and destroyed by Hurricane Katrina seven years ago. Eighty percent of our employees lost their homes and the communities they lived in were utterly devastated. We quickly opened two new facilities in the aftermath to meet the needs of our customers and provide our employees with continued employment. Both of these facilities are now at capacity.

The new facility will significantly increase our manufacturing capacity. It will be a state of the art facility for the machining, fabrication, and assembly of pharmaceutical water projects. Louisiana is a great place to work. The workforce is highly skilled and there are meaningful incentives to do projects there. Our new facility will be in Covington, LA, a New Orleans suburb located to the north of Lake Pontchartrain. Building in Louisiana is a way for us to help rebuild the community.

How does the pharmaceutical industry compare to others in considering their need to purify water?

The pharmaceutical and biotech industries are very different relative to others when it comes to many things including water. Regulations require us to start with source water that meets drinking water standards. Most other industries start with much more difficult source waters. Having said that, producing water to the Pharmacopoeia standards can be every bit as challenging and expensive. The water quality standards are high and the monitoring is more intensive as is the documentation. Regulations do not allow us to add substances, so where a simple chemical treatment step might otherwise be used, the pharmaceutical industry requires us to add additional unit operations. The manufacturing standards are significantly higher than that of general industry.

> *"In the short term, I think all of us can review our unit operations to look for opportunities to increase water recovery rates. In so doing, it is likely we will find reductions in energy usage as well.*

What other industries do you serve, how do they use your products, and are there any lessons or opportunities these industries can offer the pharmaceutical industry?

Although we serve a variety of other industries, I think the pharmaceutical industry can and will benefit from our work with the armed services. We have a long history of contracting to the US government and armed services because water is one of the largest logistical burdens on the battlefield. Right now we are under contract with the US Army, the Navy, and the

Defense Advanced Research Projects Agency (DARPA). Several years ago, the Army commissioned us to design and develop a highly capable and mobile water purification unit. Today, these machines are produced in our Texas facility and hundreds have been deployed to Iraq, Afghanistan, and elsewhere in the world. DARPA's mission is to ensure that our soldiers are never behind the technological curve, so they have commissioned us to develop the next generation of highly capable water purification units. Navy ships today operate closer to shore and in littoral waters that are troublesome for conventional desalination plants. Given this, the Navy has engaged us to design and develop an advanced shipboard desalination plant to meet their very special needs. The technologies funded, developed, and proven under these programs are done so to resolve fundamental issues that are in some cases common to other industries. The pharmaceutical industry wants lean processes and the technology being deployed and developed will result in improved water recovery, lower energy consumption, higher reliability, lower maintenance, and zero operator involvement.

Where do you see opportunities for advancement with respect to water within the pharmaceutical industry and what role can industry play in considering the larger water issue?

Water is the most prevalent ingredient in the drug manufacturing process and the pharmaceutical industry wastes an exceptional amount of water. Typically more than 25% of the feed water is rejected to waste immediately in the purification process given a variety of unit operations. Further down the line, often, only a fraction of the ultrapure water is used in the final product. In some cases, more than 90% of the freshwater (drinking water quality) supplied to a pharmaceutical water system goes down the drain. Although the technology to recycle and reuse the water is available, regulations and aversions to risk prevent us from doing so.

In the short term, I think all of us can review our unit operations to look for opportunities to increase water recovery rates. In so doing, it is likely we will find reductions in energy usage as well. Longer term, I think we need to tackle the issue of recycling and educate one another on the opportunities to do so.

ISPE has been a tremendous resource for sharing of best practices such that the process of change does not necessarily have to be accompanied by the unknown. The ISPE Baseline® Guide on Water and Steam Systems is another excellent resource for information. It is incumbent upon us to be good stewards of our natural resources and be leaders setting an example.

In considering the production of water, what technology advancements are out today that could be of benefit to the industry?

Micro- and ultrafiltration refers to a method of particulate removal. The generic process is not new and many of us are familiar with the single use cartridges used throughout the industry. The use of advanced microfiltration and ultrafiltration membranes with respect to water purification has seen exponential growth over the past 10 to 12 years, but we have not seen them widely adopted in pharmaceutical plant water systems. These membranes have the ability to be backwashed regularly, are chlorine tolerant, and offer very high recovery rates. In some cases, applying this technology can eliminate other processes or reduce the sizing of downstream processes while improving overall water quality within a system.

Given the fundamental issues surrounding water around the globe, what solutions are on the horizon?

We have been "stuck" on the use of reverse osmosis membranes for the removal of dissolved ions from water for 40 years. The principals of operation dictate certain minimum thresholds for energy consumption we just cannot get around. There are other issues around fouling of membranes and rejection rates that are undesirable and expensive. There is a tremendous amount of research underway through governmental programs, universities, and private industry. Much of it is devoted to alternative, far reaching techniques to lower the cost of water production such that it can be more economical to produce for those in need. Selective ion removal through the use of carbon nanotubes is one area that is garnering a lot of attention and money. If the theory in this area can be transformed into reality, it could have a tremendous impact on how we purify various fluids.

MECO recently launched a "Sustainability Initiative." Can you tell us a little about that and how you are implementing the initiative?

It started with the building of our new plant and our intent to be environmentally responsible with respect to our own use of water, the land around us, and the way we operate. As it turns out, we are really just committing to policy what we are doing for industry every day. We are always trying to find a solution that makes sense given the challenges. Purifying water is expensive and the operational costs over the life of a plant are many times the plant's first cost. So, in considering what we do for industry, we are always trying to improve energy consumption and reduce the water footprint. When we are successful, both the percentage and absolute value of the impact is significant.

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Global Regulatory News

International

Joint Australia New Zealand Therapeutic Products Regulatory Progress Continues[1]

Ministers from Australia and New Zealand attended the second meeting of the Australia New Zealand Therapeutic Products Agency (ANZTPA) Implementation Ministerial Council. The meeting, chaired by New Zealand Health Minister, the Hon. Tony Ryall MP, discussed progress to date on the key elements to establish a joint Trans-Tasman therapeutic products scheme and regulator. Other members of the Council attending the meeting were the Hon. Catherine King MP, Parliamentary Secretary for Health and Ageing, the Hon. Craig Foss MP, New Zealand Minister of Commerce, and the Hon. Bernie Ripoll MP, Australian Parliamentary Secretary to the Treasurer.

ICH Steering Committee Discusses Reform Aimed at Increasing Engagement of Regulators Globally[2]

The International Conference on Harmonisation Steering Committee (ICH SC) and its Expert Working Groups met in San Diego, California, USA on 10 to 15 November 2012. Building on the new principles of governance defined in Fukuoka, Japan in June 2012, the ICH SC approved procedural changes that reflect these principles. The ICH SC discussed further reform aimed at increasing the engagement of regulators globally and reiterated its commitment to the importance of harmonisation. Further progress was made on the individual topics, notably the safety reporting Guidelines E2B(R3) and E2C(R2) reached Step 4.

WHO Releases First Newsletter Tracking its Reform Efforts[3]

Change@WHO follows the developments of WHO reform; each issue will report on the three strands of programs and priority setting, governance, and managerial reform. Change@WHO will be published three times per year. The first issue can be found at: http://www.who.int/about/who_reform/change_at_who/en/index.html#.UL9r5IPAfO5.

Chinese SFDA Deputy Commissioner Bian Zhenjia Meets Deputy Commissioner of US FDA[4]

Bian Zhenjia, Deputy Commissioner of the State Food and Drug Administration (SFDA) met with the visiting Michael Taylor, Deputy Commissioner of the US Food and Drug Administration (FDA) and his entourage on 9 November 2012. Both sides reviewed bilateral cooperation in drug supervision and had adequate communication on specific issues. Main directors of SFDA's Bureau of Investigation and Enforcement, Department of International Cooperation, and relevant directors of Department of Drug Safety and Inspection attended the meeting.

Africa/Middle East

Pakistan

Pakistan Creates New Drug Regulatory Authority of Pakistan to Regulate Drugs and Medical Devices[5]

Pakistan passed the Drug Regulatory Authority of Pakistan Act, 2012 which created the new Drug Regulatory Authority to regulate drugs and medical devices in Pakistan.

Asia/Pacific Rim

Australia

Australian TGA Advances Reforms with New Advisory Council[6]

The Australian Government has appointed a group of eminent health care professionals to strategically guide the Therapeutic Goods Administration (TGA) as it implements its blueprint for reform. The Parliamentary Secretary for Health and Ageing, Catherine King, announced the membership of the Australian Therapeutic Goods Advisory Council (ATGAC), to be chaired by Australia's Chief Medical Officer, Professor Chris Baggoley. King said the appointees were selected for their individual knowledge and extensive experience in the health system.

China

Chinese SFDA Issues Guiding Opinions on Electronic Supervision of Drugs[7]

To further standardize the electronic supervision of drugs, improve work efficiency, and fulfill the tasks under the Twelfth Five-Year Plan for National Drug Safety, the State Food and Drug Administration organized the drafting and recently issued the Guiding Opinions on Electronic Supervision of Drugs based on related regulations and the Technical Guidance for Electronic Supervision of Drugs.

India

India Releases Guideline on Recalls and Rapid Alert Systems[8]

Rapid Alert System described in this

guideline is to transmit only those alerts on recalls whose urgency and seriousness cannot permit any delay in transmission. Assessment must be made of the seriousness of the defect, its potential for causing harm to the patient or (in case of veterinary product) harm to animals, consumers, operators, and the environment. The guideline can be found at: http://www.cdsco.nic.in/GuidlinesonRecall.pdf.

Japan

Japanese PMDA Issues Annual Report[9]

PMDA released its Annual Report for Fiscal Year 2011, detailing its history, objective, and operating performance. The report can be found at: http://www.pmda.go.jp/english/about/pdf/2011/annual_report_FY2011.pdf.

Japanese PMDA Issue Updates in Newsletter[10]

PMDA's newsletter, found at: http://www.pmda.go.jp/english/international/pdf/update/updates_201211_e.pdf, provides updates on sample risk management plans, the scope of PMDA's consultation on generic drugs, the implementation status of Pharmaceutical Affairs Consultation on R&D strategy, the set-up of a liaison committee for cellular and tissue based products, and various conferences and meetings attended by PMDA officials.

Europe

European Union

European Commission Facilitates Importation from Switzerland[11]

The EC implemented a decision that active pharmaceutical substances from Switzerland meet the criteria set out for importation, and will be allowed into the EU.

European Medicines Agency Increases Transparency of Human Medicines[12] Applications

The European Medicines Agency has started publishing information on ongoing applications for extensions of indication of human medicines in the minutes of the Pharmacovigilance Risk Assessment Committee (PRAC). The new level of transparency involves the publication of information on applications for changes to the authorized use of medicines where a change to the Risk-Management Plan (RMP) is needed. In these cases, the PRAC is required to provide advice to the Committee for Medicinal Products for Human Use (CHMP) on the necessary updates to the RMP. The CHMP is the committee that is responsible for making a recommendation to the European Commission on whether to grant the extension applied for or not.

Changes to EU Variation Rules[13]

A number of amendments to the Variations Regulation (Regulation (EC) No 1234/2008) that affect the provisions governing centrally authorized medicines started to apply from Friday 2 November 2012.

The amendments are described in Commission Regulation (EU) No 712/2012, which entered into force on 24 August 2012. Although their main purpose was to extend the application of the Variations Regulation to marketing authorizations granted at national level so that all marketing authorizations granted in the European Union (EU) are subject to the same rules, a number of changes affect centrally authorized medicines. These include:

- Changes to the decision-making process for variation procedures so that changes that are critical for public health are reflected in marketing authorizations within two months, while other changes are reflected in periodic updates (within one year)
- The inclusion of compliance statements with the agreed, completed paediatric investigation plan in the marketing authorization. Full details on the inclusion of the compliance statement with other technical information are available in the procedural note concerning the application of Articles 28(3), 36 and 37 of Regulation 1901/2006.

European Commission Issues Concept Paper

In an effort to prevent the entry of falsified medicines into the legal supply chain, the European Commission issued a Concept Paper, "Implementing Act on a Common Logo For Legally-Operating Online Pharmacies/Retailers Offering Medicinal Products for Human Use for Sale at a Distance to the Public,"[14] introducing a common logo for legitimate online pharmacies to clearly display on all web pages. The concept paper can be found at: http://ec.europa.eu/health/files/falsified_medicines/commonlogo_consult.pdf.

European Medicines Agency on Track to Meet 2012-15 Business Targets

The European Medicines Agency's Management Board discussed the Agency's annual mid-year report for 2012 at its meeting on 4 October. The mid-year report from the Executive Director to the Management Board provides an overview of the Agency's progress from January to June in implementing its 2012 work program.

Presenting the report to the Board, Executive Director Guido Rasi said that the progress of the Agency's activities so far in 2012 was encouraging. "Our main performance indicators have been met. The mid-year report indicates that the Agency is on target to meet its core business objectives for 2012," he said.

Finland

Finnish Medicines Agency Revises Clinical Trials[16] Regulation

Finnish Medicines Agency's Administrative Regulation 2/2012 entered into force on 1 December 2012, replacing earlier Regulation 1/2007. The overall

substance of the Regulation remains unchanged. Following changes are done:

- The Investigator's Brochure must be validated/updated annually (Directive 2005/28/EC of the European Commission).
- The data elements in reports to be made of unexpected serious adverse reactions (SUSARs) have been adjusted (Note for guidance - EudraVigilance Human - Processing of safety messages and individual case safety reports (ICSRs) EMA/H/20665/04/Final Rev. 2).
- The requirement concerning annual safety reporting (list of suspicion of serious adverse reactions and a report signed by the person responsible for a trial on the safety of persons participating in a clinical trial has been specified to be in force throughout the period a trial is in progress in Finland (Detailed guidance on the collection, verification, and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use 2011/C 172/01 (CT-3)).
- Plasma-derived medicinal products used in a clinical trial on medicinal products have been added to the sphere of Fimea's batch-specific release.
- The data concerning preclinical studies as well as investigational medicinal product has been revised to correspond to the regulations in force.

Finnish Medicines Agency Posts New Contact Details[17]

The Finnish Medicines Agency Fimea started using the new Government telephone service from 12 November 2012. At the same time, the Agency adopted new telephone numbers with the 0295 prefix; the old 09 numbers no longer work. Mobile telephone numbers will remain unchanged. The number for the new switchboard is +358 29 522 3341.

The new service was implemented by stages in all central government agencies, one of the main objectives being to increase operational flexibility and create savings. Another objective for the change at Fimea is improved accessibility of personnel. In connection with the change, Fimea also adopted a new corporate postal code to make postage between offices go more smoothly. In the future, Fimea's post will be delivered to: P.O. Box 55, FI-00034 FIMEA, FINLAND.

First Finnish National Medicines Day[18]

The National Medicines Day was a national day for both medicine users and health care professionals. "Know your medicines" was the theme of the first National Medicines Day, taking place on 6 November 2012 on the initiative of Paula Risikko, Minister of Social Affairs and Health.

Ireland

Irish Medicines Board Publishes 2011 Annual Report[19]

The IMB published its annual report for 2011, a year which marked the 15th anniversary of its establishment as a national regulatory authority. The key activities and achievements for 2011 highlight the significant program of work delivered across the organization. Of particular note were a 10 percent increase in the number of new product applications approved in respect of human medicines and a 16 percent increase in the number of enforcement cases involving breaches of medicinal product legislation.

North America/South America

Canada

Health Canada Issues Draft Guidance on GMPs for APIs[20]

On 29 September 2012, proposed regulatory requirements amending the Food and Drug Regulations to extend Good Manufacturing Practices requirements to active ingredients, together with the Regulatory Impact Analysis Statement (RIAS) for the proposal, have been pre-published for public consultation in the Canada Gazette, Part I. The present draft document Good Manufacturing Practices (GMP) for Active Pharmaceutical Ingredients (APIs) Guidelines (GUI-0104) provides interpretive guidance for the manufacture of APIs as per the proposed regulatory amendment. The guideline can be found at: http://www.hc-sc.gc.ca/dhp-mps/consultation/compli-conform/2012-gui-0104-eng.php.

United States

US Lawmakers Pledge Action After Meningitis Outbreak[21]

Democratic and Republican lawmakers vowed they would alter the regulation of drug compounding pharmacies in hopes of preventing more crises like the rare fungal meningitis outbreak that has now cost many lives.

US FDA Provides Information on Impact of Weather on Biological Products[22]

CBER is providing interested persons with information concerning the storage and use of temperature-sensitive biological products that have been involved in a temporary electrical power failure or flood conditions. While people should not be put at risk by using a product that may be unsafe due to the conditions under which it was stored, shortages should not be created by discarding product simply because of power failures that may not adversely affect the product. Vials of biological products in contact with flood waters should be discarded given the possibility of contamination and the likelihood of significant exposure to temperatures outside of those recommended for cold chain storage.

Most biological products require specific storage conditions, as indicated in the product labeling, to maintain their safety, purity, and potency. These products include

bacterial and viral vaccines, allergenic extracts, plasma derivatives, and other products requiring refrigeration or frozen storage, as well as products that can be stored at controlled room temperature (i.e., not exceptionally cold or hot). When there is an electrical power failure, whether due to accident, equipment failure, or disruption in the electrical power grid, the temperature control systems for product storage may not function. For example, on 14 August 2003, the northeast region of the country experienced a power outage lasting from one to several days, and some health professionals were uncertain what to do with products that they had in storage. Power failures are not only a concern regarding storage in a facility, as failure of the refrigeration or freezer unit on a carrier (e.g., truck) while the products are in transit also may occur. The information below may assist interested persons in determining what to do with their biological products in the event of a power failure.

During normal business hours, questions may be directed to 1-800-835-4709. After business hours, parties may call the FDA emergency operations line at 301-796-8240. These questions will be forwarded to the appropriate Center or office for advice.

US FDA Works with Partners to Establish Important Data Standards[23]

A new partnership between the FDA, the Clinical Data Interchange Standards Consortium (CDISC), and the Critical Path Institute (C-Path) was officially launched at the CDISC International Interchange in Baltimore. This partnership, called the Coalition for Accelerating Standards and Therapies or CFAST, will bring together clinical data experts from the FDA, the pharmaceutical industry, and the information technology sector, to develop and maintain data standards tailored to individual diseases and therapeutic areas.

US FDA Commissioner: State and Local Partnerships are Crucial[24]

Margaret Hamburg, FDA Commissioner, discussed in a blog entry the importance of state and local partnerships in light of the recent meningitis outbreak. She stated, "In the face of this current tragedy, we are all working hard—together—to fully contain the health risks associated with this outbreak as quickly as possible to protect patients and the nation's medical drug supply."

US FDA Celebrates 50-Year Anniversary of Kefauver-Harris Amendments[25]

The Food and Drug Administration celebrated the anniversary of the passage of the Kefauver-Harris drug amendments, which have ensured prescription drug effectiveness and safety for 50 years. But the legislation may not have been proposed if not for the persistence and grit of an FDA medical officer and two US congressmen. Frances Kelsey, in reviewing the new drug thalidomide, refused to bow to pressure to approve it quickly, and discovered that it caused severe birth defects when taken for morning sickness by pregnant women. Many babies with these birth defects had been born in Europe, where the drug was approved, and Kelsey made the connection between thalidomide and the defects. Two years earlier, Senator Estes Kefauver of Tennessee was decrying the lack of clear federal regulation in the area of drug approval. He called for revisions of the drug statutes; few people listened, especially in Congress. The thalidomide tragedy gave rise to broader calls for drug controls and unearthed Kefauver's bill to enhance drug regulation. Representative Oren Harris was chairman of the Committee on Interstate and Foreign Commerce. During his final term in the House, he introduced and sponsored the Drug Abuse Control Act, which required certain "stimulant, depressant, or hallucinogenic" drugs to require licensing before sale and distribution. He was the lead House sponsor of the Kefauver-Harris Amendment.

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ASEAN Harmonization on GMP Inspection and Training of Inspectors

by Sia Chong Hock, Robert Tribe, and Dr. Chan Lai Wah

This article provides a progress report on the harmonization of GMP inspection and training of inspectors being led by the Association of Southeast Asian Nations (ASEAN).

Background

The Association of Southeast Asian Nations (ASEAN) was founded in 1967, and it comprises 10 Southeast Asian Member States. In alphabetical order, they are Brunei Darussalam, Cambodia, Indonesia, Laos, Malaysia, Myanmar (Burma), Singapore, Philippines, Thailand, and Viet Nam. A map of Southeast Asia is shown in Figure 1.

The 10 ASEAN Member States have very diverse racial, religious, socio-cultural, political, economic, and geographical backgrounds. Hence, the task of integrating ASEAN is a highly challenging one. However, ASEAN has the political will and resolve to create an ASEAN Economic Community (AEC), as it is aware of the economic competition that it faces from its larger Asian neighbors as well as other economic powers from the rest of the world. They include (with their population in brackets), Taiwan (23 million), South Korea (49 million), Japan (127 million), India (1.2 billion), China (1.3 billion), Australia (22 million), Canada (34 million), United States (314 million), and the European Union (about 500 million).[1]

Collectively, ASEAN as a 10-member group, is not small. A key strength of ASEAN is its combined population (and potential market) of about 600 million people. This can be turned into a big economic advantage if rules and regulations are harmonized, and made transparent. If not, ASEAN will face strong competition globally and it will not be an attractive destination for potential investors.

Need for ASEAN Economic Integration

On 2 September 2003, ASEAN leaders agreed at the 35th ASEAN Economic Ministers Meeting in Phnom Penh, Cambodia, to establish an ASEAN Economic Community (AEC) by 2020. The AEC is expected to develop ASEAN into a highly competitive region of equitable economic development, with a single market and production base, which is fully integrated into the global economy.[2]

On 29 November 2004, the ASEAN Secretariat issued a media release entitled "ASEAN Accelerates Integration of

Figure 1. Map of Southeast Asia.

Figure 2. ASEAN: One Vision, One Identity, One Community. ASEAN Pharmaceutical Products Working Group Meeting – Yogyakarta, July 2010.

Priority Sectors" following the 10th ASEAN Summit in Vientiane, Laos. This ASEAN Framework Agreement on Integration of Priority Sectors represented a major step toward the realization of AEC. Eleven priority sectors, including health care, of which pharmaceutical products are a component, were identified. An ASEAN Sectoral Mutual Recognition Arrangement (MRA) on GMP Inspection for Manufacturers of Medicinal Products, was one of the priority initiatives.[3] On 13 January 2007, the Cebu Declaration on the Acceleration of the Establishment of an AEC by 2015, was signed at the 12th ASEAN Summit, held in Cebu, Philippines. The Cebu Declaration accelerated the establishment of AEC from 2020 to 2015.[4]

ASEAN MRA Taskforce on GMP Inspection

With the AEC 2015 as the backdrop, and an ASEAN Sectoral MRA on GMP Inspection as one of the priority initiatives, an ASEAN MRA Taskforce on GMP Inspection was formed in 2005. This taskforce was charged with the responsibility to deliver the ASEAN Sectoral MRA on GMP Inspection for Manufacturers of Medicinal Products, as its main outcome. Singapore and Malaysia were appointed as the Chair and Co-Chair of this taskforce respectively, as both Singapore and Malaysia were the only two ASEAN Member States that were members of the Pharmaceutical Inspection Co-operation Scheme (PICS) based in Geneva. The PICS inspection framework had been used as the basis for working out the ASEAN Sectoral MRA on GMP Inspection, i.e., ASEAN Member States had agreed to adopt the PICS inspection framework as its benchmark.

Altogether, the ASEAN MRA Taskforce on GMP Inspection held seven round table meetings in six different ASEAN cities between 2005 and 2008. The first meeting was held in August 2005 in Singapore, where the terms of reference, benchmark, and framework of the MRA were agreed upon. The second meeting was held in March 2006 in Hanoi, where a GMP gap analysis was conducted among the 10 ASEAN Member States, presented, and discussed. By the third meeting in October 2006 in Jakarta, a technical working draft of the MRA was put up for discussion. A special (adhoc) technical meeting was held in April 2007 in Hanoi, where the legal aspects and implications of the MRA on all 10 ASEAN Member States were scrutinized. At the fourth meeting in July 2007 in Kuala Lumpur and the fifth meeting in February 2008 in Vientiane, Laos, the contents of the MRA were further deliberated to "ensure that no stones were left unturned." By the sixth meeting in July 2008 in Brunei Darulssalam, there was consensus on the contents of the ASEAN Sectoral MRA on GMP Inspection, from both technical and legal perspectives, and the MRA was ready to be signed in 2009 as targeted.[5]

The ASEAN Sectoral MRA on GMP Inspection for Manufacturers of Medicinal Products was signed by the Economic Ministers of all 10 ASEAN Member States on 10 April 2009 in Pattaya, Thailand. This MRA comprises 19 Articles as shown in Table A.

Under Article 4, the scope of the MRA covers medicinal products in finished dosage forms, and they include both Over-The-Counter (OTC) and prescription medicines. However, the scope of the MRA excludes Active Pharmaceutical Ingredients (APIs), biologicals, and traditional and herbal medicinal products. Under Article 8 of the MRA, ASEAN

Article 1	Definitions	Article 11	Implementation
Article 2	Objectives	Article 12	Termination of Listed Inspection Service
Article 3	General Provisions	Article 13	Preservation of National Drug Regulatory Authority
Article 4	Scope and Coverage	Article 14	Confidence Building
Article 5	Designating Body	Article 15	Confidentiality
Article 6	Joint Sectoral Committee	Article 16	Rights and Obligations
Article 7	Listing of Inspection Service	Article 17	Dispute Settlement
Article 8	Mutual Recognition Obligations	Article 18	Deferral of Implementation
Article 9	Verification of Competency	Article 19	Final Provisions
Article 10	Technical Competence		

Table A. Nineteen Articles of ASEAN Sectoral MRA on GMP Inspection for Manufacturers of Medicinal Products.

Figure 3. Seventh Meeting of ASEAN MRA Taskforce on GMP Inspection, Manila, 27 May 2009.

Member States are obliged to operate a PICS-equivalent GMP inspection framework. They are also obliged to accept the GMP certificates or inspection reports issued by the listed Inspection Services, i.e., the inspectorates of ASEAN Member States whose GMP inspection systems meet the PIC/S framework.[6]

Since the signing of the ASEAN MRA in Pattaya on 10 April 2009, three more MRA taskforce meetings had been held. These (post-MRA) meetings were held in Manila (May 2009), Yogyakarta (July 2010), and Singapore (June 2011) respectively. Although the ASEAN MRA was signed in 2009, ASEAN Member States agreed to give themselves a two-year grace period before its implementation in 2011. The mood at these post-MRA taskforce meetings was generally more relaxed than the pre-MRA taskforce meetings for the simple reason that the MRA had been signed, sealed, and delivered. The delivery of this first MRA in ASEAN for the pharmaceutical sector was regarded as a landmark achievement.

The final ASEAN MRA taskforce meeting was held in Singapore on 7 June 2011. After the meeting in Singapore, the taskforce was dissolved and a Joint Sectoral Committee (JSC) established, to oversee the implementation of the MRA, which had come into force in 2011.

Implementation of the ASEAN Sectoral MRA on GMP Inspection

Since the signing of the MRA in 2009, some initiatives associated with the implementation of the MRA had been carried out while awaiting for the MRA to come into force in 2011. These initiatives included:

- The preparation of a set of Frequently Asked Questions (FAQs) about the ASEAN Sectoral MRA on GMP Inspection for Manufacturers of Medicinal Products. This set of FAQs was uploaded on the ASEAN website at www.asean.org in 2010.
- The preparation of an Operation Manual on Panel of Experts. This Operation Manual was approved as an internal ASEAN quality system document in 2011.[5]

With the establishment of JSC, following the dissolution of the ASEAN MRA Taskforce in 2011, ASEAN inspectorates (Inspection Services) can now apply for listing. The proce-

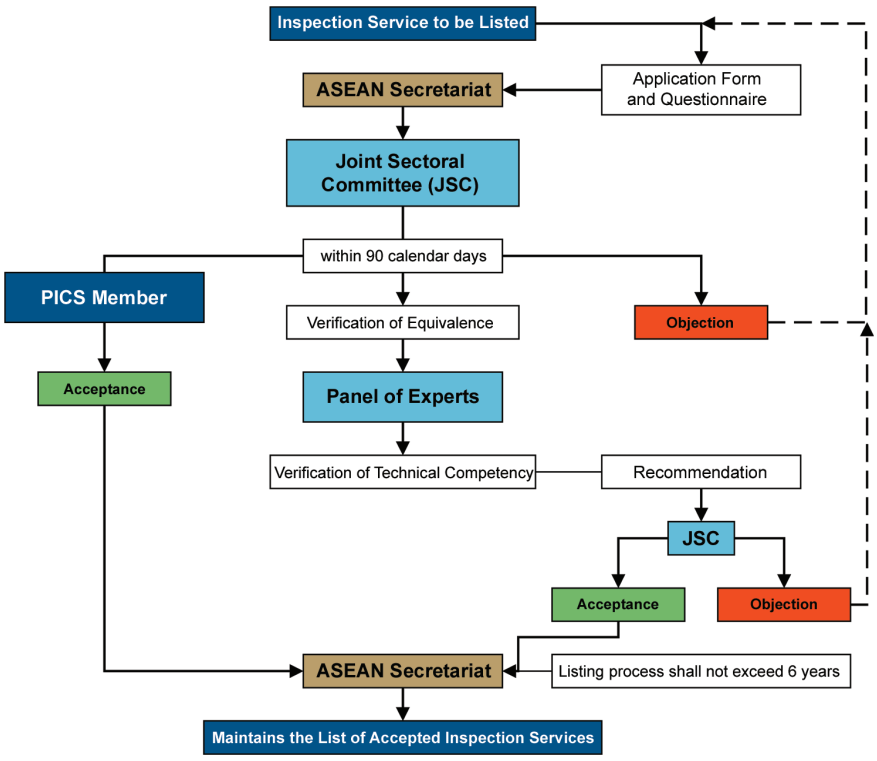

Figure 4. Flowchart of Procedure for Listing an ASEAN Inspection Service.

dure for listing an ASEAN Inspection Service is provided for under Article 7 of the ASEAN Sectoral MRA on GMP Inspection. A flow-chart of the listing procedure is shown in Figure 4.

Essentially, an application for listing is submitted by an ASEAN Inspection Service to JSC through the ASEAN Secretariat. JSC shall inform the ASEAN Secretariat of the outcome of application within 90 calendar days. ASEAN Member States which are PICS members shall be listed without any further assessment. If further assessment is required (as in the case of an ASEAN Member State which is not a member of PICS), a Panel of Experts will be formed by JSC to carry out the verification of competency as provided for under Article 9 of the ASEAN Sectoral MRA on GMP Inspection. Upon completion of the technical assessment, the Panel of Experts will submit its recommendation to JSC for concurrence. A list of accepted Inspection Services will be maintained by the ASEAN Secretariat.[6]

Currently, the National Drug Regulatory Authorities of three ASEAN Member States, namely Singapore, Malaysia and Indonesia, are members of PICS since 1 January 2000, 1 January 2002 and 1 July 2012 respectively. Based on the procedure for listing, Singapore Health Sciences Authority (HSA), Malaysia National Pharmaceutical Control Bureau (NPCB), and Indonesia National Agency for Drug and Food Control (NADFC) can be listed without any further assessment, and they are ready to exchange GMP certificates and inspection reports.

The implementation of the ASEAN Sectoral MRA on GMP Inspection is expected to bring about many benefits to ASEAN Member States. These benefits include:

- The avoidance of duplication of GMP inspections within the 10 Member States of ASEAN
- Saving of time, resources, and costs for both the ASEAN regulators and the industry
- Facilitation of import, export, and overall trade in medicinal products across the ASEAN region
- Quicker access of medicinal products by ASEAN patients
- Increased competitiveness of ASEAN as a group, viz-a-viz, India, China, Japan, and other bigger industrialized countries of the world

In order to achieve maximum benefits from the MRA, ASEAN would need to level up the inspection system of all its National Drug Regulatory Authorities to meet the PICS framework. This leveling up process also would need to incorporate a program for training and continual training of ASEAN GMP inspectors.

Training of ASEAN GMP Inspectors

Why is the training of an inspector so important? The popular sport, soccer (football), will be used as an analogy. In the game of football, the manufacturers are like the players while the inspectors (such as those from the United States FDA, Australia TGA, European Union EMA and ASEAN) play the role of the referee. The referee has the unenviable tasks of confronting any errant player, blowing the whistle when rules are not obeyed, and issuing the yellow and red cards when rules and regulations are flouted repeatedly. The referee also has to prevent football from becoming footbrawl, where the game becomes unruly and players fight with one another or with the referee, and the field and stadium may be set on fire. The key role of the referee is to maintain a level and orderly field where the football players abide by the rules of the game. In a similar manner, the inspectors have to maintain a level playing field for the pharmaceutical manufacturers using the PICS GMP standard or other equivalent GMP codes and the legal requirements, as the yardstick.

Thus, the training of the referee or the inspector is very critical, and there is a need to level up the competency of ASEAN GMP inspectors. Competency encompasses the educational qualification, experience, training, and skills sets (both hard and soft skills) of the GMP inspector. In Singapore, many of the GMP inspectors have a pharmacy or pharmaceutical science educational background from the National University of Singapore, and most have relevant industry experience before they join the Singapore Health Sciences Authority as GMP inspectors. Both hard and soft skills sets are crucial to the performance of a GMP inspector in the field. The hard skills sets expected of a GMP inspector include knowledge of:

- Pharmacology (covering drug actions, indications, contra-indications, etc.)
- Pharmaceutical Chemistry (including drug syntheses and analyses)
- Pharmaceutical Microbiology (including sterilization and disinfection processes)
- Pharmaceutical Technology (including manufacturing processes and their controls)
- Pharmaceutical Laws (i.e., Medicines Act and Health Products Act)
- GMP and Quality Standards (including validation and stability studies)

Most of the hard skills are covered in the existing Pharmacy undergraduate program of the National University of Singapore. However, in addition to this, a GMP inspector also would need to possess inter-personal and soft skills set, such as confidence, assertiveness, professional integrity, fairness, perseverance, tact, and diplomacy. He also should have good oral and written communication skills, including the ability to put up a clear unambiguous inspection report in a narrative format using standard English.

As the professional knowledge and skills of a GMP inspector have to remain current and relevant, a continual training program for all ASEAN GMP inspectors has to be put in place. As a first step toward developing this continual GMP training program, a Training Needs Analysis (TNA) was conducted in 2010. This TNA was a collaborative effort between the ASEAN MRA Taskforce on GMP Inspection and ISPE. The key objectives of this TNA survey was to find out the preferred topics for GMP training of ASEAN inspectors, their preferred training delivery methods; and to explore ways and means to make GMP training more effective and appropriate for ASEAN inspectors. The TNA was conducted via an online survey from May to June 2010. A questionnaire was sent to all ASEAN GMP inspectors. The survey was carried out on an "anonymous" basis, i.e., no personal details were requested from the inspectors. Altogether, 71 ASEAN GMP inspectors responded, and this figure represented about 30% of the total number of inspectors within the ASEAN region. The responders included trainees, qualified inspectors, as well as managers and heads of ASEAN inspectorates.[5]

The key findings of the TNA survey are as follows:

- 17% indicated training needs in cross contamination control
- 26% indicated training needs in pharmaceutical water systems
- 30% indicated training needs in facility design and layout
- 13% indicated that they have no formal training in PICS GMP standard
- 12% indicated that they have no formal training in the PICS Quality System Requirements for Pharmaceutical Inspectorates

The TNA survey also highlighted variation in training methodology and training frequency among ASEAN Member States, and a strong preference by ASEAN inspectors for training methods which offered mock inspections, hands-on experience, practical training with case studies, and not just theoretical classroom lectures. These findings were presented at the ninth meeting of the ASEAN MRA Taskforce on GMP Inspection, held in Singapore in June 2011. ISPE was invited to this meeting. ISPE was represented by Robert Tribe and Linda Ambrose. It was a highly fruitful ISPE-ASEAN meeting.[5]

Figure 5. Ninth Meeting of the ASEAN MRA Taskforce on GMP Inspection, Singapore, June 2011, with participation from ISPE.

At the ninth ASEAN MRA Taskforce Meeting, ISPE suggested a three-tiered GMP inspector training curriculum comprising:

- Level 1: Induction training for recruits
- Level 2: PICS GMP training for trainee inspectors
- Level 3: Specific subject training for qualified inspectors

Training delivery methods that were explored included coached (mock) inspections, classroom training sessions, online training courses (conducted via "live " or recorded webinars), and the publication of guidance documents for use as educational and reference materials. However, there are several challenges and issues that need to be sorted out. Going forward, the new ASEAN Joint Sectoral Committee (which has taken over from the ASEAN MRA Taskforce) would have to decide on the appropriate training methods for each module, identify trainers with industry and regulatory experience, identify trainees with the potential to become trainers (for continuity of the program), seek out companies which can provide venues for coached (mock) inspections, and most importantly, to determine the overall costs and identify funding sources for the training program.[5]

Conclusion

ASEAN needs to harmonize its pharmaceutical regulations in response to the establishment of an ASEAN Economic Community (AEC) by 2015. The establishment of AEC is critically needed to turn ASEAN into a highly competitive region of equitable economic development with a single market and production base, which is fully integrated into the global economy.

The good thing is that an ASEAN Sectoral MRA on GMP Inspection has been agreed upon by all ASEAN Member States and signed in 2009 by all its 10 Economic Ministers, using the PICS GMP inspection framework as the benchmark. A Joint Sectoral Committee (JSC) has been established to oversee the implementation of this ASEAN Sectoral MRA on GMP Inspection for Manufacturers of Medicinal Products. As part of the implementation of this MRA, ASEAN is actively collaborating with PICS, ISPE, and other stakeholders to level up its inspectorates, as well as the competency of its GMP inspectors. The ASEAN inspectorates are aware that no regulatory authority can work in isolation in a globalized world with its associated sets of challenges. The way forward is collaboration, collaboration, and more collaboration.

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Automating a Manual Cleaning Program in a Multi-Product Biopharmaceutical Manufacturing Operation

by Gordon Leichter, PhD, and John Spohn, CPIP

This article discusses how to implement automatic washing in facilities where manual washing is conducted and provides valuable insight into lessons learned and key considerations in the planning for their future-state process.

Introduction

This following discussion provides an overview of a representative project entailing renovation of a substantial equipment cleaning program from manual to automated methods. The project was in a biopharmaceutical facility that produced several different bulk drug substances in separated process trains. Cross contamination was a major concern in all phases of the project development and implementation.

Existing Situation

The facility was a first-generation biopharmaceutical facility which had evolved to house close-quarter manufacture of multiple products. In the original plant design, CIP and SIP were employed for large vessels and lines, but the majority of cell culture, harvest, and purification equipment was broken down after each use and the parts treated through a Clean-Out-of-Place (COP) program of manual parts cleaning using soak tanks.

Manual cleaning carries risk to the process because it is so dependent on rigorous and consistent performance of sometimes arduous physical tasks while wearing elaborate PPE by a variety of individuals. Even the most dedicated operators will occasionally make an error. As new production processes were introduced over the years, the incremental expansions to the cleaning program were accommodated until its performance began to suffer both in terms of rework and schedule impacts.

Similarly the handling of parts in strong caustic solutions and manual HWFI rinses eventually produced safety inci-

Figure 1. Manual washing utilizing soak tanks.

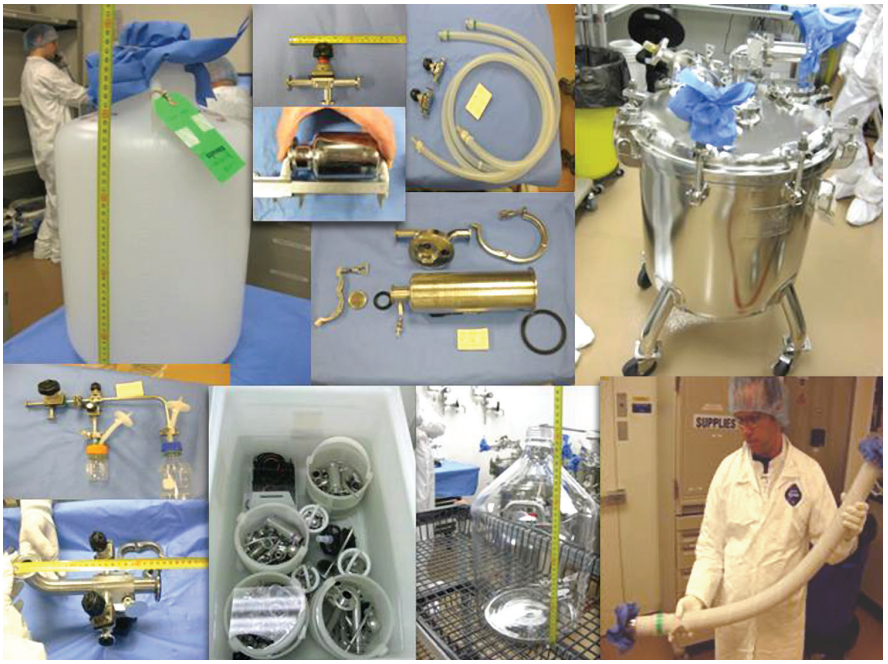

Figure 2. Example of items from assessment.

dents that were thankfully minor, but were clear indications that revisions should be immediately considered. The prospect of applying more rigorous cleaning validation standards to massive manual program made it clear that the time had come to automate the operation.

The subject COP processes involved a minimum two hour static soak in 0.5 molar NaOH then 3x manual HWFI rinse at 85°C for small parts. Parts too big for the soak tanks received a series of manual applications of cleaning solution and rinses. Bottom line, the manual COP approach was:

- Inefficient
- Inconsistent
- Difficult to document
- Difficult to trace
- Hazardous to personnel

An automated washer addresses many of the aforementioned concerns and challenges, but it is not the focus of this article. Actually, a principal challenge to projects of this nature is excessive focus on "the box," or washing machine; which will be addressed later in the article.

Basic Project Elements

The approach to automating a manual washing process involves four principal elements:

1. Make a meticulous inventory of wash items
2. Select an automatic parts washing machine and design its installation
3. Design the work flow of the wash items
4. Select and design wash racks

Element 1 – The Wash Item Inventory

Based upon the wide variety of items to be washed, the owner's team initially identified about 100 different items representing the extremes of the wash item inventory. The largest items were selected to set minimum wash cabin dimensions and parts with the most difficult to clean configurations were selected for wash rack design considerations.

After the award of the project to the supplier, two wash rack engineers worked for two weeks with a team at the owner's site compiling a catalog of wash items with dimensional information. The assessment identified more than 150 assemblies that comprised about 550 unique parts. Producing one complete final bulk of each product required COP of more than 3,400 parts - *Figure 2*.

Element 2 – Selection of the Automated Washer

Accommodating large portable vessels and the substantial volume of wash items indicated a pit-mounted, large capacity GMP washer that allows for items to roll in and out at floor level - *Figure 3*.

Typically, capital project teams planning and executing equipment cleaning implementations focus on basic equipment design and engineering facets like capacity (cabin size and throughput), footprint and utility requirements. Automating large-scale manual COP is more than equipment upgrades; however, it is a total upgrade of cleaning operations which requires a higher level of analysis of the facility and its procedures.

Several key factors must be vetted before machine design is finalized. For example, legacy utility systems may meet the daily de-

Figure 3. Large capacity pit-mounted CGMP Washer.

mand for pharmaceutical waters, but if these systems are unable to support the instantaneous demands, day tank(s) must be designed into the washer unit. The installation must be able to fit the washer, which is another consideration. Rigging paths must be analyzed to determine whether large components of the washing machine may be brought safely to that location. In this case, the washer cabin was shipped in two pieces and welded together in place.

Business continuity is another consideration – the higher capital demands of a multi-washer installation may be justified by the avoided risks posed by staking productivity to a single train of machines.

The equipment cleaning operations should be reviewed for required or opportune improvements in flow of parts and personnel, mitigation of cross-contamination risk, HVAC impacts – rezoning or new AHU, space utilization and storage of wash racks an accessories.

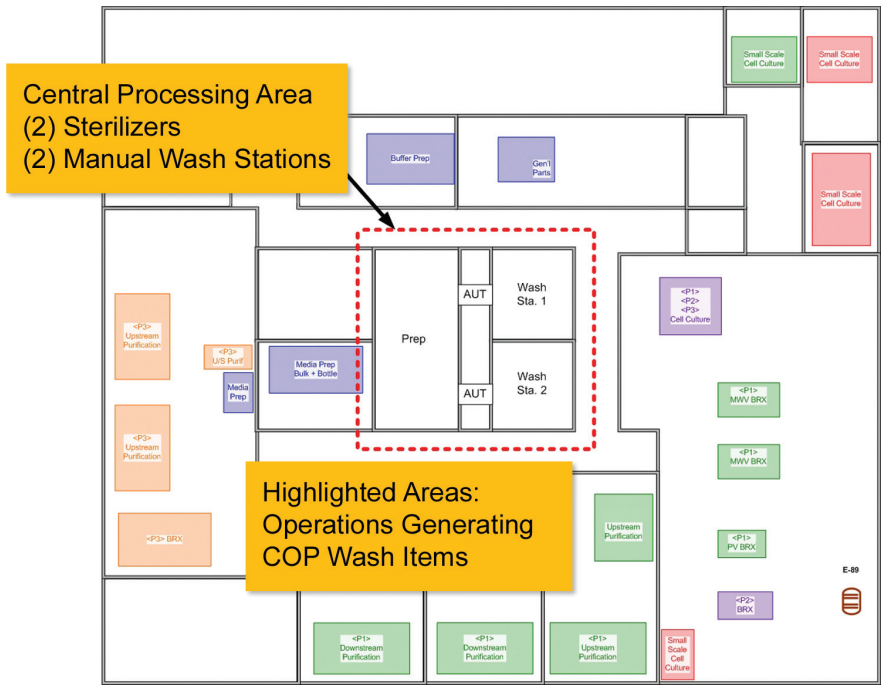

Figure 4. Original work layout.

Element 3 – Work Flow: The Epiphany

The team's epiphany about the key to a successful implementation came when working on Element 3 – the Work Flow. As engineers, we tend to focus on the equipment and the respective details of how it functions: finishes, software, documentation, etc. And the work on elements 1 and 2 made it clear to the team that the real challenge of the project was something other than knowing what was going to be washed and picking a machine to do it.

The essence of the project would be an informed design of the future flows of parts through their full utilization cycle: from post-process to cleaning to sterilization to storage, ready again for process use. These flows would ideally produce "kits"of parts comprising everything needed to support a procedure or unit operation much like surgical kits are prepared in hospitals; and do it with greater operational efficiency and reduced cross-contamination risk than manual COP.

This realization prompted the project team to take a step back, analyze the current flows of wash items and identify what really needed to be changed in the facility to obtain the best advantage from automated washing.

Figure 4 depicts the segregated work areas and the central processing area for cleaning and sterilization. Post-use

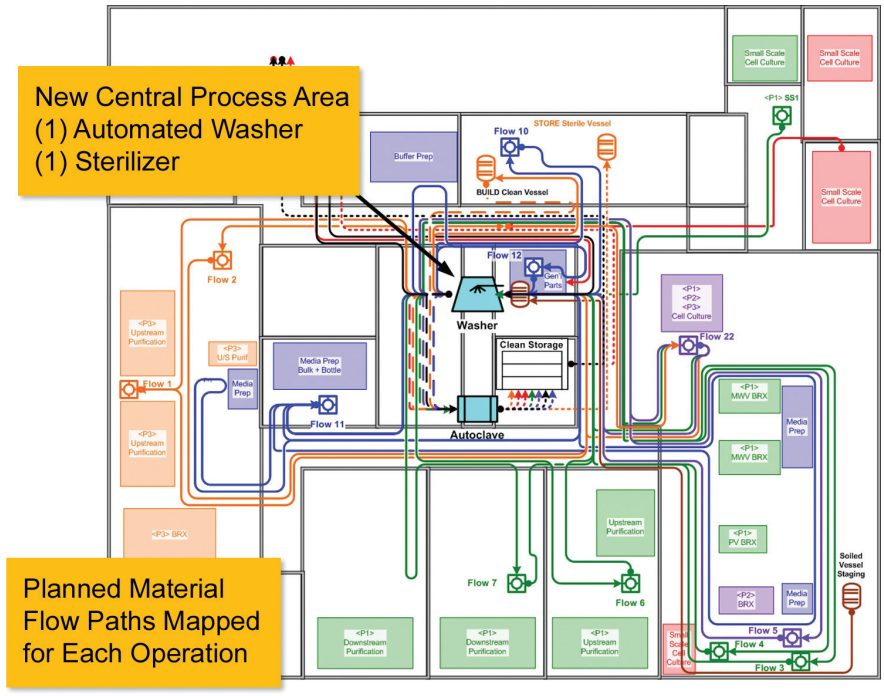

Figure 5. Realized material work flows.

		FLOW Rack Number (Capacity)	<P1> US1 465 (1/2) 424 (1/2)	<P1> US2.1 466 (1/1)	<P1> US1.1 465 (1/2) 424 (1/2)	<P1> US1. 466 (1/1)	<P1> DS2.1 465 (1/2) 424 (1/2)	<P1> DS2.1 465 (1/1)	<P1> DS2.1 465 (1/2) 424 (1/2)	<P1> DS2.4 466 (1/1)	<P1> DS2.1 465 (1/2) 424 (1/2)	<P3> GC1 467 (1/4)	<P4> GC2 467 (1/4)	<P5> GC3 467 (1/4)
Ident	**Wash Item**	**Kit**	**1**	**2**	**1**	**2**	**1**	**2**	**1**	**2**	**1**	**3**	**3**	**3**
X-30	Dip Tubes		4											
X-31	Depth Filter Plates		2											
X-32	Depth Filter Center Post		1											
X-34	Depth Filter Compression Nut		1											
X-35	"T" type Filter Bases		5	1	1	1	1	2	2	2	2			
X-36	10 ltr Carboy						1							
X-37	20 ltr Carboy						1							
X-38	50 ltr Carboy													
X-39	Carboy Caps			1			2							
X-41	Diverter Tube							2	2	2	2			
X-42	J Tube				1									
X-43	ø1½" × 30" lg diptube													
X-44	ø2" × 30" lg diptube													

Figure 6. Sample section of "kitting" document.

wash items moved from the work areas into manual wash station rooms. Operators from each department performed the manual cleaning of their department's wash items and then visually inspected and prepared them for storage or autoclaving. The small number of rooms required elaborate room changeover procedures to be performed each time a different classification of wash items required processing.

The legacy manual processes needed improvements in control. Documentation was used to track the soak tanks and large, manually cleaned vessels. On introduction, new processes or wash items were subject to cleaning validation, but swabbing was not conducted on a regular basis. The washers provide an automatically documented and repeatable cleaning process verified through conductivity monitoring of wash solutions as well as inline conductivity and TOC monitoring of waste water discharges. They also alleviate the manual labor and hazard to personnel.

Re-evaluate the Work Flow

As the project progressed, the realization was that this was not a straightforward project to install automated washers, but a complete conversion of equipment cleaning work flow from a reactive, demand-driven model to a proactive, schedule-driven model.

The project team deployed to analyze the master list of parts from several perspectives: What items were required to support each operation; from where did they come to the cleaning operation, then where did they need to be staged, ready to use; when did the items need to be processed: daily, weekly, quarterly, etc? Each of these analyses was vital to developing wash rack designs and operational strategy.

Figure 5 depicts the different flow paths from the different manufacturing operations through the facility. The project team identified a material flow path for the components for each manufacturing operation that required cleaning and/or sterilization.

After gaining a good understanding of how wash items needed to move through the facility, these flows needed to be organized and enumerated – down to the last gasket. Figure 6 is a portion of the tables that were developed to identify "kits" of parts required to support specific manufacturing operations.

The development of the kitting documents was a significant effort involving discussion with operators and supervisors in all other departments generating COP wash items. Each wash item was cataloged and associated with a location and association to other wash items. Each wash item was measured and recorded. This information became the basis for the development of custom wash racks. This exercise also helped to identify the quantities of wash racks that needed to be developed, as well as identifying locations for storage of these racks.

Element 4 – The Wash Racks

Element 4 is the Wash Racks, which secure wash items inside the wash cabin and ensures consistent cleaning and good drainage. See Figure 7.

A fundamental decision in a project like this is selecting the approach to wash rack and load design because it has profound impact on the effectiveness of the washing process and capital requirements. Work flow analysis and planning of the nature described

Figure 7. Typical wash rack for large wash items.

here proves to be indispensable. Also, it must be made very early in the project's development – the first rounds should be undertaken to provide detailed project requirements to prospective suppliers.

The fundamental choice is between: a) using a standard rack design with meticulous procedures and removable attachments and b) designing racks for specific kits. The generic "dishwasher" approach is desirable because there are fewer racks to purchase, qualify and store. Faced with a large number of difficult-to-clean item configurations the team reasoned that the additional upfront work and expense of designed-for-purpose racks would pay off in years of simplified, more repeatable operations.

The key user requirements were for the rack designs to:

1. Align with the flows so parts supporting specific unit ops would be processed together – minimizing the number of required runs and burden on utilities
2. Be specific for each load to provide repeatable exposure to highly complex parts
3. Provide the ability to reliably service the complete COP requirement with the minimum number of wash racks - responding to the limited storage space available and minimization of number of runs while avoiding packing the parts too densely
4. Provide suitable containment to eliminate risk of cross contamination as well as the need for elaborate room changeover procedures

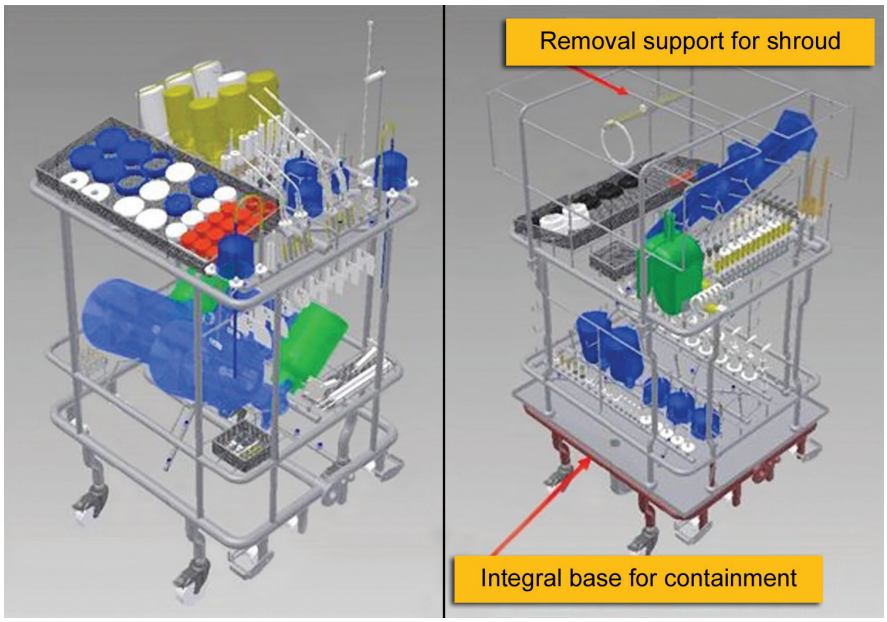

Figure 8. 3-D Models of each wash rack and material load.

Wash Rack Design Development

As the "kitting" documents were developed, the wash racks were designed. Each wash item was modeled in 3-D software and grouped together in respective loads. Each wash rack was given a specific number and assigned to an operation. 3-D models were reviewed and approved by the project team. Figure 8 is an example of some of the designs and details generated.

Because some components could still contain liquids or residue after disassembly, some wash racks were designed with drip pans to capture the liquid and contain it during movement through the facility. The drip pans had drain valves that would be opened by the operators once loaded into the washer. Also, a removable upper support was included for the placement of a disposable shroud to cover the entire cart to mitigate potential cross contamination.

The above described process ultimately resulted in 15 unique wash rack designs and a total of 27 wash racks to accommodate the immense range and volume of wash items. The initial estimate was for only nine wash racks based upon

	Product P3						P3												
	Product P2						P2				P2	P2	P2	P2	P2	P2	P2	P2	P2
	Product P1	P1	P1	P1	P1	P1	P1									P1	P1	P1	
	General	G	G	G	G	G	G	G	G	G	G	G	G	G	G	G	G	G	
	Kit	1				2	3	4			5		6			7	8		
	Rack	1A		1B		2	3	4			5A	5B	6A		6B	7	8A	8B	
Ident	Wash Item Load >>> v v v v v v v	1A1	1A2	1B1	1B2	2A1	3A1	4A1	4A2	4A3	5A1	5B1	6A1	6A2	6B1	7A1	8A1	8B1	
X-5	Filter stand																		
X-6	½" valve (diaphragm)											1	1				20		
X-7	1" valve (diaphragm)												1						
X-8	1½" valve (diaphragm)											1	1						
X-9	2" valve (diaphragm)											1							
X-11	Stainless steel reducers											2							
X-11.1	SS Reducer 1½" to ¾"			7	4	10		5			5	5			5				
X-11.2	Reducer ½"																		
X-11.3	SS Reducer 1½" to ½"	7	7	7	4	10		5			5								
X-12	Stainless WFI extension piece																		
X-14	1" stainless steel caps														3				
X-14.1	4" stainless steel caps	X				1							1						
X-14.2	¾" stainless steel caps	12	25			10						10			8				
X-14.3	2" stainless steel caps														3				
X-15	3" stainless steel caps											5							
X-16	1½" stainless steel caps	12	25			10						10			8				
X-20	Hose 1" with TC 6'											1			1				

Figure 9. Sample section of a "load" document.

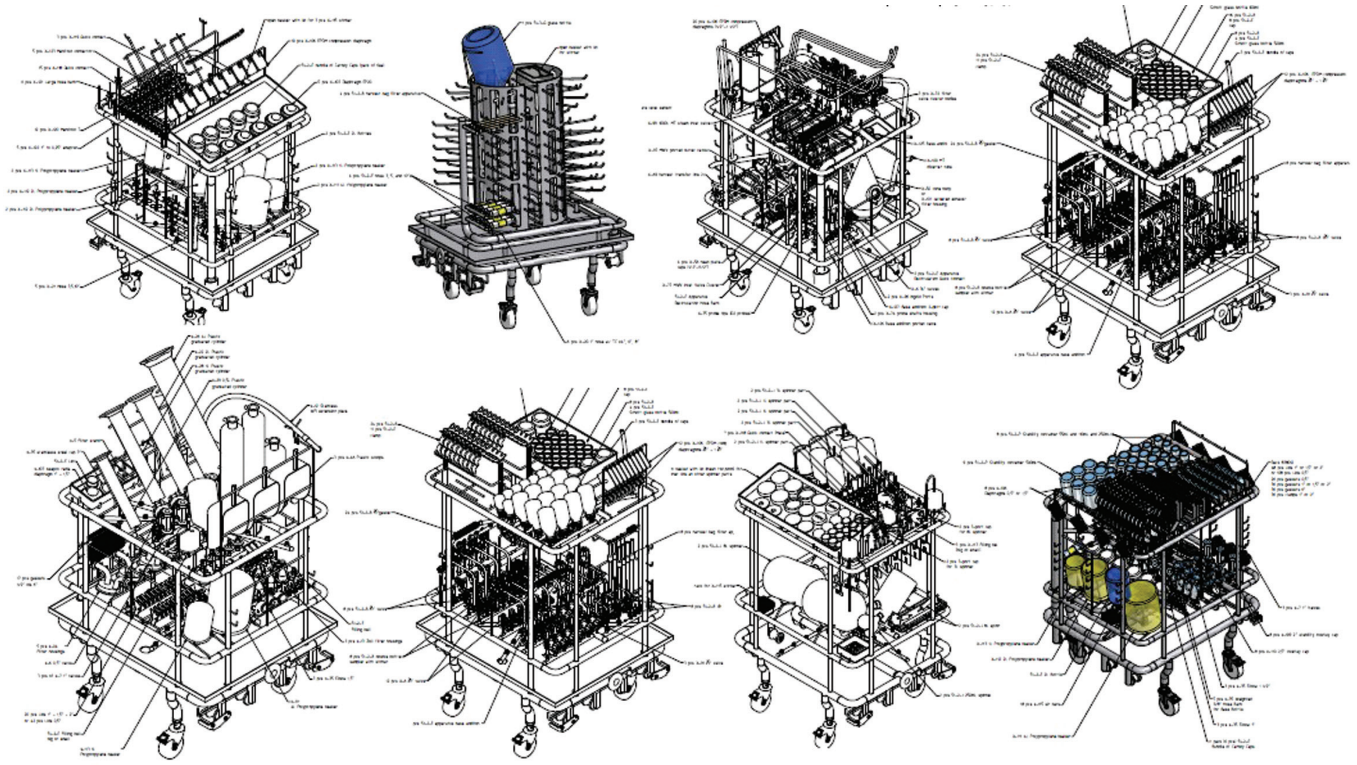

Figure 10. Example of customized wash racks developed for the project.

the URS with an allowance for a few more if needed. Having a three-fold increase in wash racks was a challenge for the project team. Wash racks are in a range of $20 to 30,000 each, depending on complexity.

The final resolution of the rack designs to the kitting document produced the "load" document that describes the complete relationship between the required kit, the rack(s) needed to reliably clean all the items in the kit, the specific load patterns to be processed and the quantity of each wash item in a load - *Figure 9*.

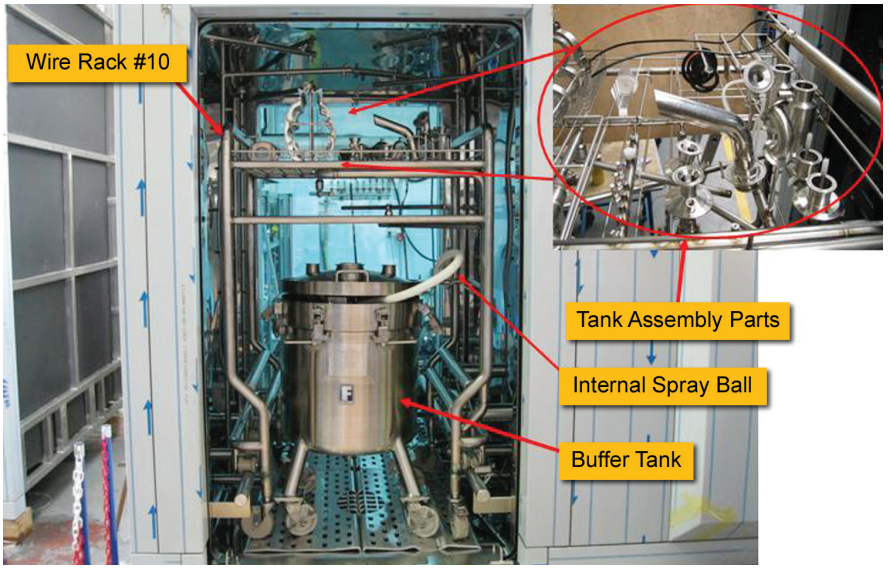

Figure 11. FAT of a wash rack for portable vessels and components.

The load document and the 3-D models became the basis for the Preparation and loading SOPs. Document specialists used the 3-D models to create a sequence of visual aids that illustrate the loading process stepwise, from the perspective of the person performing the loading activity - *Figure 10*.

Another challenge with the wash racks on the project was, as stated earlier, a disproportionate focus on "the box" rather than how it would be used. The development of the "kitting" process was not initiated until after bid award, which then drove the design and quantities. It took many months longer than anticipated to finalize the design and manufacture of all the wash racks. The design and manufacturing capacity requirements were severely underestimated as well as the costs to the end users.

Process Development

The starting approach for the washing process was existing CIP recipes known to successfully remove the soils of interest. Samples of soiled wash items and CIP recipes were sent to a third-party detergent supplier for analysis and recommendations on washing chemistry. The detergent supplier provided recommended concentrations of detergents, and durations and temperatures for washing and rinsing, which were readily programmed into the control system of the washers.

Advantages gained by the automation included the elimination of manual conductivity and TOC testing at the critical steps, resulting in time savings and higher quality assurance. While there is a sense of cost reduction through the enhancements made by eliminating the manual work required by operators, the true financial gain is realized through improved quality and personnel safety, which is hard to measure financially.

CQV of the Washing Operation

A clear challenge for any project of this nature is qualification and validation, especially cleaning validation. This is profoundly true for a project dealing with so many parts flows and multiple products. At this writing, the equipment is installed and in qualification. The cleaning validation of the process is planned, but has not commenced.

Qualification for the equipment and installation were arduous, but unremarkable. The two aspects that warrant discussion here are the qualification of the wash racks and cleaning validation approach.

As the wash racks were built and delivered they were inspected for damage and conformance with design – materials of construction, dimensions, capacities, and the fit-up of wash items was verified. Spray coverage was verified through customary riboflavin testing for the wash items on their racks as well as for the ability of the washer to maintain its own cabin in a clean state.

Coordinating a ready supply of wash items for fit-up and other qualification activities proved much more difficult than anticipated and impacts to qualification and production schedules resulted. Availability of wash items should be a key consideration for future projects whether for new installation or renovation.

The notion of setting aside a dedicated supply of key wash items is usually dismissed out of hand as economically unsupportable, but it is principally because the massive coordination efforts, delays in qualification, or disruption of production are viewed as avoidable and not assigned tangible value. We recommend it be seriously considered and at an early enough point in the project development to ensure the supply is available for use throughout the lifecycle of the washing process.

A principal consideration for cleaning validation was whether to employ product specific assays to detect product residues. Due to a substantial difference in nominal dose sizes between products, the Maximum Allowable Carryover (MACO) calculations indicated extreme limits of residues, one well above WFI standards and another well below the limits of detection of all available product-specific lab methods.

The quandary was resolved through specification of detergent products that could be shown to completely degrade the proteins of interest. As a result, the validation program calls for swab samples from the equipment and wash items to be analyzed for the non-specific products of product degradation as represented by TOC.

Operator Training

With any new system, operator training and acceptance is an essential part of the qualification process. The team approached this by tapping qualified operators as key participants in all stages of project development and execution and in particular to develop the training materials and programs under the tutelage of the training department. In this, the detailed 3-D models provided a valuable resource to produce images for all documents presented in ways determined to be most effective for operators, by operators. The training on how to set components on wash racks and make proper connections produced a high degree of right-first-time riboflavin coverage testing, a harbinger of reliable and effective operations for the future.

Conclusion

The purpose of this article is to share some experiences on a project that many pharmaceutical production facilities face. Manual washing of production components is quite common. While the installation of a new machine is the prominent tangible change of the project, the real work of establishing a program of automated washing is the planning for a successful program.

Some key aspects to be considered to make such an undertaking more effective are:

- Select a supplier to work with early on in the project, preferably before budgeting.
- Develop a lifecycle approach to the assessment of wash items and work flows in the earliest stages of the project and work it though the lifecycle of the equipment.
- Plan wash item availability from initial measurements through factory acceptance testing, CQV, and requalification activities.
- Involve all stakeholders in the assessment of the washer operation, especially end users of wash items and those responsible for planning of cleaning validation.
- Evaluate space requirements for wash racks and storage.
- Treat the development of the wash racks as a critical path item on the project.

It is important to note that a qualification plan for a project of this nature should be focused upon at the beginning. Decisions on what science-based technologies will be used to assure cleaning is achieved can drive important design criteria later on in the project.

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Expanding the Process Validation Paradigm and Applying it to the Biopharmaceutical Product Lifecycle from Development through Commercial Manufacturing

by Mark F. Witcher, PhD

This article presents a combination of critical process and product definition issues with a QbD approach to define the Validation Lifecycle Matrix (VLM) used to build a Validation Master Plan (VMP) that guides development of the product through its complete lifecycle.

Introduction

The FDA's 2011 Process Validation Guidance[1] is an insightful and very useful document that covers many of the issues required to successfully develop and manufacture high quality biopharmaceuticals. When combined with the approaches defined in the FDA's Q8(R2) – Pharmaceutical Development,[2] the PV Guidance provides the foundation for operational excellence in all phases of the product's manufacturing operations. One of the keys to successful commercial biopharmaceutical manufacturing is to view process validation as part of the overall product development effort. The 2011 PV Guidance was likely developed and structured using this viewpoint; however, the 2011 PV Guidance does not explicitly identify and fully cover all the points that are vital to successfully developing and manufacturing biopharmaceuticals. As a regulatory based document, it was probably not intended to cover all the issues; however, the approach can be applied to essentially all phases of the product's development. The purpose of this article is to broaden the use of the paradigm to identify and define these critical elements and provide a foundation for understanding and applying the approach described in the 2011 PV Guidance.

FDA's 2011 PV Guidance states:

> *"Process validation involves a series of activities taking place over the lifecycle of the product and the process. This guidance describes process validation activities in three stages:*
>
> ***Stage 1 – Process Design:*** *the commercial manufacturing process is defined during this stage based on knowledge gained through development and scale-up activities.*
>
> ***Stage 2 – Process Qualification:*** *during this stage, the process design is evaluated to determine if the process is capable of reproducible commercial manufacturing.*
>
> ***Stage 3 – Continued Process Verification:*** *ongoing assurance is gained during routine production that the process remains in a state of control."*

The above definitions provide an excellent regulatory framework; however, to use this process validation approach to its maximum effectiveness for building an efficient and highly reliable commercial manufacturing capacity, the definitions need to be expanded, generalized, and "industrialized" to focus on all the important issues. For the PV paradigm to be successfully executed, as many items as possible must be clearly identified for early consideration and inclusion in the execution of the entire product development sequence.

The first set of items is a clear definition of the product and the process required to successfully make the product. The product and process definitions must go significantly beyond just defining the Critical Quality Attributes (CQAs) and the Quality Target Product Profile (QTPP). As will be discussed below, many items must be defined in order for the product and process development efforts to be initiated in the direction that leads to success. Because these items are so important, an additional stage, Stage #0 – Product and Process Definition will be added to the process validation paradigm.

> *"For the PV paradigm to be successfully executed, as many items as possible must be clearly identified for early consideration and inclusion in the execution of the entire product development sequence.*

The second set of items is related to the activities required to successfully operate a commercial manufacturing enterprise. The FDA's PV Stage 3 describes the ongoing verification effort that assures that the process is performing as it was designed. In any manufacturing enterprise, how the facility and process are operated is critical to consistently and reliably producing high quality product. For this reason, the Stage 3 element of the paradigm will be expanded to explicitly include a wide variety of operational issues.

Add Product and Process Definition – Stage #0–(Define)

One of the great strengths of ASTM E-2500[3] is its emphasis on defining clear requirements before proceeding to the design phase. In biopharmaceuticals, properly defining the product is a crucial prerequisite to developing a successful manufacturing process capable of making the product for pre-clinical testing through to the commercial manufacturing phase. The definition phase includes critical issues from selecting the cell lines and building cell banks to defining capacity requirements early in the product's development. For example, understanding the Post Translational Modification (PTM) profile of the product is important in selecting a cell line capable of expressing the product protein with the required biological activity.

Some of the activities that need to be included in Stage #0–Define are:

- Estimate product's QTPP, including:
  - Critical Quality Attributes (CQAs), including:
    - > Post translational modifications
    - > Purity requirements, etc.
- Select cells line candidates capable of providing the product with the estimated QTPP
- Estimate material requirements to supply the market
- Based on the QTPP and material requirements, select options for:
  - Process Unit Operations (UO) configurations (e.g., batch, perfusion, etc.) and sequence capable of meeting product demand
  - Bioreactor configurations and upstream yield targets
  - Downstream processes capable of providing sufficient product purity and yields
- Define and plan process development resources
- Estimate capital investment requirements for clinical and commercial manufacturing
- Estimate Cost of Goods (COG) targets
- Define Intellectual Property (IP) positions related to the process and product technologies
- Draft outline of a Validation Master Plan (VMP)
- Define and plan other tasks, activities, resources, and milestones required to define the product, process, and the entire development effort

In addition, Stage #0–Define should include other critical activities required to eventually launch the product. For example, the approach, scope, scale, and resources for completing the clinical trials should be estimated to assure that sufficient resources are available in order to complete product development. Unfortunately, many candidate products fail in product development before getting a fair test in the clinic to determine their therapeutic value. Many of these failures are due to incomplete and/or poor planning in Stage #0–Define.

While many of these items are nearly impossible to estimate accurately, particularly early in the product's development, identifying, estimating (educated guessing), and clearly stating these as assumptions are critical to the product's long

term success. Bluntly stated, when these and other definition items are not identified and addressed, they become buried assumptions, which if left unaddressed, can lead to product, and in the case of small companies, business failures.

An old saying in biotech is "make the product fail quickly," and Stage #0–Define is the best place to start identifying critical issues and possible failure modes of the product and the product development effort. If reasonable estimates cannot be made for all the definition items, subsequent research and development needs to focus on identifying a path to a reasonable set of assumptions that provide a path to success. These assumptions then become the focus of considerable effort to establish the viability of the product. If the issues cannot be resolved, the obvious questions of product viability are raised.

Expand Stage 3 – Continuous Process Verification

The second critical PV stage that needs a more in-depth definition is Stage 3. In successfully operating a manufacturing facility, verification is only one of many long term operational issues that must be addressed. While the PV Guidance certainly covers a wide variety of operating issues in spirit, it does not call for the explicit, systematic identification of all the issues that need to be addressed for operating a manufacturing enterprise. The entire manufacturing enterprise must be run and controlled with a focus on excellence rather than just compliance. Excellence is achieved by building a set of highly integrated and mutually supportive operating systems which include all the tasks and activities to operate and control a complex manufacturing facility. To emphasize the operational element, Stage 3 will be called Stage #3–Operate/Verify. Worthy of note is that product and process control, and its integration into operations is a major component of operating a facility. Thus the stage could easily be called Operate, Control, and Verify.

Stage #3–Operate/Verify should include activities related, but not limited to:

- Execution of manufacturing procedures that produce clear, concise batch and manufacturing records
- Control of the process according to established control algorithms
- Implementation of training and personnel performance monitoring policies and procedures
- Execution of maintenance, preventive maintenance, and calibration programs
- Execution of change control and Corrective Action - Preventive Action (CAPA) programs
- Implementation of qualitative and quantitative data review and assessments programs, including the use of Statistical Process Control (SPC) methods, where appropriate
- Use investigation systems, including Out-Of-Specification (OOS) and near-miss event programs
- Implement ongoing internal and external executive monitoring and review programs
- Implement Real-Time Release Testing (RTRT) release methods, and intra and inter batch reviews
- Review and set limits for CQAs, Critical Process Attributes (CPA), Critical Process Parameters (CPP) with ongoing review and updating
- Pre-Approval Inspection (PAI) planning, preparation, and execution
- Use other systems required for long term operation of the manufacturing facility

The next step is to take these two paradigm additions and assemble them into an expanded process validation paradigm for application to developing biopharmaceutical products.

Expanded Process Validation Paradigm

Incorporating the issues described above and more formally integrating and generalizing the development concepts of ICH Q8(R2), the expanded process validation paradigm can be summarized in the following four stages:

Stage #0: Product and Process Definition (Define) – define requirements (Basis of Design (BOD)) during product development. Specifically focus on estimating, defining, and refining the Quality Attributes, QTPP, product manufacturing requirements, and the process' Design Space. Identify and plan resource requirements for development phases. Initiate, develop, and refine the Validation Master Plan (VMP).

Stage #1: Process Design (Design) – based on the applicable BOD, complete product and process development design and development. Specific focus is on the development of the process and other resources, including the facility and infrastructure, used to manufacture the product. Primary activities are to develop and understand the process, and build the Q8 Design Space model of the process.

Stage #2: Process Qualification (Qualify) – establishes that the process and/or facility designed in Stage #1 produces the required product as defined in the BOD and Design Space. Stage #2 also qualifies the surrounding infrastructure and the facility's ability to successfully run the process. For the commercial phase, Process Performance Qualification (PPQ) batches are produced.

Stage #3: Continuous Operation and Verification (Operate/Verify) – establishes an appropriate program during the product lifecycle to assure that the facility and

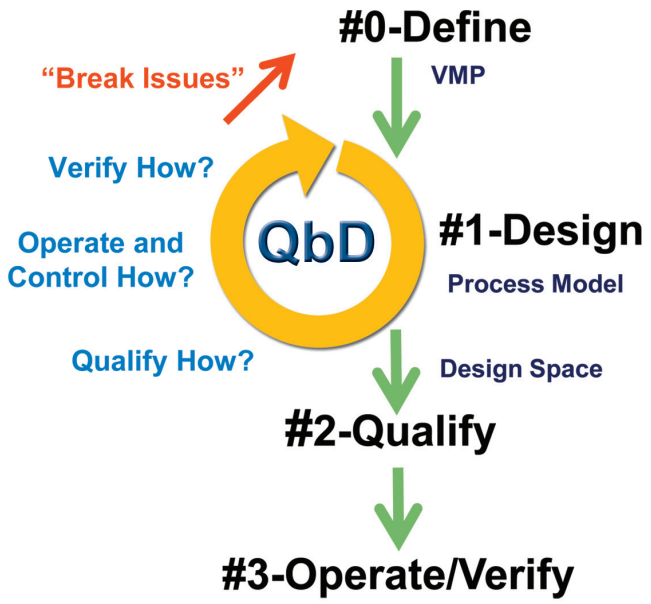

Figure 1. The Process Validation/QbD Paradigm. After the #0–Define stage is complete, the #1 Design stage continues in an iterative fashion until clear approaches to Qualify, Operate, Control, and Verify the process are determined. When a "break issue" is identified which cannot be designed around, then a return to the #0–Define stage may be required. When the #1 Design stage is complete, then the #2 Qualify and #3 Operate/Verify stages can begin.

process continues to operate as defined in the Design Space and continues to produce product with the same QTPP as specified in the IND, BLA, and tested in the clinical trials and approved by regulatory agencies.

An important concept is that the four process validation stages are separated to some extent from the product development sequence and generalized to apply to all phases of the product's development. With the process validation paradigm expanded to cover the wide variety of critical issues, understanding how to use PV paradigm begins by applying Quality by Design concepts to the execution of the paradigm.

Using Quality by Design (QbD)

While many of the above activities and systems are not directly process related, they interact with the process and greatly influence how the process and manufacturing facility operate, particularly over the long haul. All the infrastructure systems listed above should be defined, designed, qualified, and operated in concert with each other. One feature of the 2011 PV Guidance is that they represent an excellent forward looking methodology for applying Quality by Design (QbD) to building the process, manufacturing facility, and all the internal infrastructure systems in concert with each other. One approach is to apply the PV paradigm using QbD to every system. The PV/QbD paradigms can be combined as shown in Figure 1.

The QbD paradigm is the engine that drives Stage #1–Design. QbD is a very powerful concept with wide utility for achieving any goal or building any enterprise. Although a great deal of confusion surrounds the term, QbD is a very simple concept. QbD can be more concisely described as "Success by Design." Basically, QbD focuses on answering the questions:

- What will success look like? (Stage #0)
- During Stage #1, what must be done to be successful? (Stage #2 and #3)

In Figure 1, the paradigm starts with the Stage #0-Define where important requirements described above are identified. The next step is to enter the Stage #1-Design where the requirements are used to outline the initial design. The design outline can be viewed as a conceptual process vision or model. With the initial design concepts established, the QbD paradigm is then used in an iterative fashion during process development to define how the process will be qualified, controlled, operated, and its performance verified during manufacturing. Stage #1-Design includes process development and the tools described in the Q8(R2), particularly the Design Space and the FDA's 2011 PV Guidance. As the performance, qualification, operation, and verification questions are answered, the design is modified to accommodate and optimize the requirements identified in Stage #0-Define. All the information is captured in the Design Space and Validation Master Plan (VMP). If any critical issues are identified that cannot be resolved ("break issue"), the definition assembled in Stage #0–Define may have to be modified as shown in Figure 1. For example, if the target process yields for viable COGs cannot be reached, the cell line may need to be changed or modified. Once Stage #1–Design has reached the point where qualification, control, operation, and verification elements are understood and the VMP elements in place, then the Stage #2–Qualify and Stage #3–Verify/Operate stages can begin.

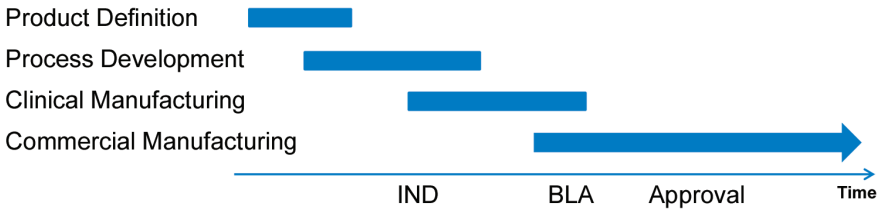

Figure 2. Relative Timeline for Product Development Phases.

To use the process validation paradigm over the entire product development and commercialization effort, a clear understanding of the entire product manufacturing lifecycle is required. The four PV validation stages and their interaction with the large number of activities and tasks required to successfully commercialize the product needs to be identified and coordinated. The following represents a method of integrating the four process validation stages with the various phases of product development.

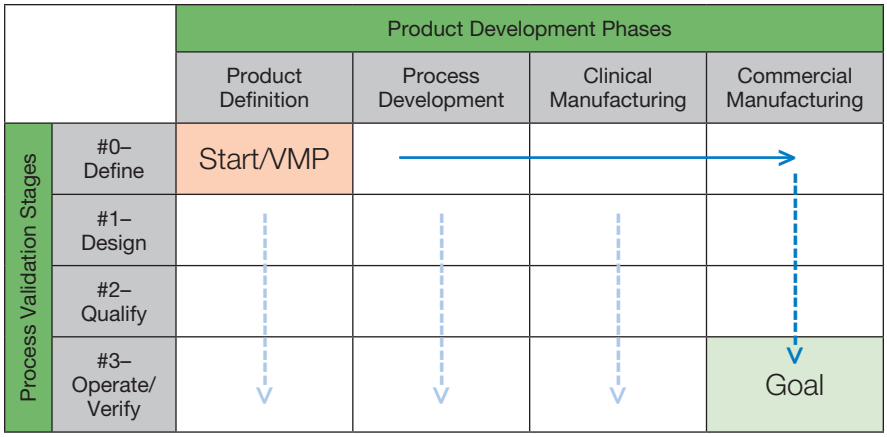

Figure 3. Validation Lifecycle Matrix (VLM) – A tool for understanding the relationship between the Process Validation Stages and the Product Development Phases required for commercializing a product.

Validation Lifecycle Matrix

Different companies have a wide variety of approaches for developing biopharmaceutical products; and thus have a wide variety of names for their various product development phases. All the phases interact and overlap extensively. For discussion here, the following four phases represent the irreducible minimum, and thus will be used to illustrate the concept and issues associated with using the process validation paradigm. The product development phases are:

- Product Definition
- Process Development
- Clinical Manufacturing
- Commercial Manufacturing

The typical relative timeline for each development phase is shown in Figure 2. To understand the product lifecycle, the four Product Development Phases are combined with the four Process Validation Stages to yield the Validation Lifecycle Matrix (VLM).[4] The Product Development Phases shown in Figure 2 are different than the Process Validation Stages identified above. As will be shown, each Product Development Phase goes through all four Process Validation Stages. The basic VLM for the entire product development lifecycle is shown in Figure 3.

As will be shown, the VLM is a tool for understanding and using the PV paradigm to define and direct the overall product development and validation effort. The VLM is used both horizontally and vertically to identify and address the large number of issues necessary to reach the ultimate goal of a licensed, operating commercial manufacturing facility. The VLM is a major element of assembling and integrating the VMP.

Product development starts with defining and planning in the upper left and proceeds in both vertical and horizontal directions using the iterative generalized QbD approach previously discussed to develop the VMP. The initial VMP is developed by taking each product development phase and assembling the requirements of each phase and stage to reach the final goal. As stated earlier, a lot of assumptions and estimates must be made to develop the VMP. These assumptions must be made, documented, tracked, and tested as the development effort proceeds. To ignore them is to risk failure in the middle by not adequately dealing with critical

		Product Development Phases			
		Product Definition	Process Dev.	Clinical Mfg.	Comm. Mfg.
Process Validation Stages	#0–Define	• Define CQA • Estimate capacity required • Select cell type • Create MCB/WCB • Draft initial VMP			
	#1–Design	• Define: - Resources - Development Strategy - UO Sequence - Design Space Outline			
	#2–Qualify	• Define Qualification: - Strategies - Resources			
	#3–Operate/Verify	• Draft process control strategy • Draft RTRT strategy			

Figure 4. Validation Lifecycle Matrix (VLM) for the Product Definition Phase. Critical product and process foundations are established with input drawn from other elements of the VLM.

Process Validation Stages	Product Development Phases			
	Prod. Def.	Process Development	Clinical Mfg.	Comm. Mfg.
#0–Define		• Establish development goals • Identify resources required		
#1 – Design		• Define UO Sequence, etc. • Process Development: - DOE experiments - Build Design Space - Control Strategy - Scale-up • Make preclinical material • Write IND		
#2–Qualify		• Achieved development goals? • Draft performance criteria		
#3–Operate/Verify		• Process support functions • Problem solving		

Figure 5. Validation Lifecycle Matrix (VLM) elements for Process Development Phase. Primary goals are to define and optimize the UO sequence and build the Q8 – Design Space using DOE and other experimental methods.

issues in a timely manner and in the necessary sequence. Few things are more deadly to a product's development than "discovering" a major issue in the middle of the development and commercialization process. Many issues are manageable when anticipated, but may be untenable when identified after specific development paths have already been taken. One example is discovering the process yields are too low to support viable manufacturing costs after the clinical trials have been initiated.

Process Validation Stages	Product Development Phases			
	Prod. Def.	Process Dev.	Clinical Manufacturing	Comm. Mfg.
#0–Define			• Define clinical VMP • Estimate clinical material required	
#1–Design			• Prepare Clinical Mfg. Facility, or • Build clinical capacity	
#2–Qualify			• Qualify clinical facility • Qualify Clinical vs. Preclinical Matl. • Qualify control strategy	
#3–Operate/Verify			• Manufacture Clinical Material • Verify clinical batches • Monitor clinical manufacturing • Write BLA/NDA • Draft RTRT strategy • Identify SPC opportunities • Draft CPA, CPP limits	

Figure 6. Validation Lifecycle Matrix (VLM) elements for the Clinical Manufacturing Phase. Both Stage #2 and #3 assure high quality product to the clinic, as well as generate valuable information for building the Design Space for the Commercial Manufacturing Phase.

Product Definition Phase

As discussed earlier, the Product Definition Phase is evaluated in terms of the four PV stages. Figure 4 shows some of the tasks and activities that are required. The initial VMP is a compilation of all the tasks and activities identified. The VMP is then expanded by addressing the issues raised in analyzing the rest of the product development phases.

Drafting a VMP is a crucial first step and should cover all the important issues to be faced. The VMP is a dynamic document that should be updated frequently as more is learned about the product, process, resources, and timelines constraints and requirements.

The VMP tool also can be used for individual activities, Unit Operations (UO), or any other element of the product development effort. The VLM, QbD approach, and PV paradigms can be effectively used to develop plans and strategies for everything from commercial manufacturing facilities, training programs, high purity water monitoring programs, and any other program or enterprise. Similar diagrams or plans can be developed for specific UO to identify all the tasks and activities required to successfully operate the UO in a commercial facility. For example, a similar matrix could be developed for a bioreactor or chromatography UO skid. The VLM is used to systematically identify everything that needs to be done and the goals that need to be accomplished using the QbD approach discussed earlier to assure the UO is properly defined, designed, and developed for commercial manufacturing.

Process Development Phase

After most of the product definition phase is completed, the product development phase begins as outlined in Figure 5. Stage #0–Define of the Development Phase is used to plan the development effort, establish the goals to be achieved, and identify the resources required to accomplish the goals.

Stage #1–Design lists some of the activities required to design a process. Obviously this list depends on the product and the process; and may be quite complex and convoluted depending on the progress made by the development team to reach Stage #0 goals. The QbD

approach should be used to address the qualification and operating/control/verification issues for both clinical and commercial manufacturing phases as outlined in the VMP.

After the process is designed, other Stage #1–Design activities would include pilot runs, production of pre-clinical material, and supporting the compilation and writing of the IND. Initial estimates of process' performance measures such as alert/action limits and process variability criteria can also be estimated. Stage #3–Operate/Verify issues are those needed for long term process support and problem solving associated with clinical and commercial manufacturing phases. Resource requirements and goals for these items should be estimated and appropriate provisions made for supporting the clinical and commercial manufacturing operations.

All the process development/validation activities represent investments, in many cases very large investments, in the product's development. The timing and sequencing of these activities should be determined by a cost/benefit analysis based on the product's value and the desired schedule to reach the market. A fast track approach would dictate large investments in parallel activity paths, while more conservative investment approaches may be sequentially timed on "proof of concept" and "go/no-go" milestones.

Clinical Manufacturing Phase

Following process development and the manufacturing of preclinical material, the Clinical Manufacturing Phase begins. Obviously, the primary goal of the Clinical Manufacturing Phase is to supply the clinic with appropriate material for clinical testing; however, clinical manufacturing provides a wide variety of opportunities to gain experience with the process and expand the process' Design Space. Some of the VLM elements for the Clinical Manufacturing Phase are shown in Figure 6.

Stage #0–Define of the Clinical Manufacturing Phase estimates the clinical material requirements, which include identifying the location to be used to make the material. Depending on the approach taken, a clinical manufacturing facility may have to be constructed which would add to the complexity of all the Clinical VLM and VMP activities. The Clinical VLM tasks for a new facility are not shown in Figure 6. After appropriately qualifying the clinical facility, the clinical material would be manufactured using appropriate GMPs. Stage #3–Operate/Verify also would provide an opportunity to begin drafting CQA, Critical Process Attributes (CPA), Critical Process Parameters (CPP), and Critical Control Parameter (CCP) limits for commercial manufacturing. Other opportunities include evaluation of SPC methods, draft RTRT approaches, etc.

Commercial Manufacturing Phase

Figure 7 shows the VLM for the Commercial Manufacturing Phase. The number of tasks in the commercial phase can be very large depending on what manufacturing scenario is selected. In the case of designing, building, and validating a new facility, the VLM would include all the relevant tasks. The identification of those tasks and activities is outside the scope of this article; however, Stage #0-Define and Stage #1 - Design are the stages used to define, design, and construct the commercial manufacturing facility. Stage #2–Qualify is used to qualify the facility and manufacturing infrastructure, including the running of PPQ batches, to show that the facility and its infrastructure can operate and control the process as it is described in the Design Space.

Stage #2–Qualify is also used to produce the launch inventory for supplying the initial product demand and to prepare for the Pre-Approval Inspection (PAI). Once the facility is approved, then commercial manufacturing begins under Stage #3–Operate/Verify, and the long term operational programs, including control schemes and verification tools, for the commercial facility are implemented and used.

		Product Development Phases			
		Prod. Def.	Process Dev.	Clinical Mfg.	Commercial Manufacturing
Process Validation Stages	#0–Define				• Define commercial VMP • Define commercial material required
	#1–Design				• Design/Build new facility, or • Match process to existing facility?
	#2–Qualify				• Qualify commercial facility • Execute PPQ Batches • Produce launch inventory • Qualify control strategy • Prepare for Pre-Approval Inspection
	#3–Operate/Verify				• Complete Pre-Approval Inspection • Produce commercial material • Establish and use RTRT program • Set CPA, CPP limits • Setup and implement SPC program • Establish and use change control, CAPA

Figure 7. Validation Lifecycle Matrix (VLM) elements for Commercial Manufacturing Phase. Emphasis is placed on getting the facility licensed and the production of commercial material for the long term.

Conclusion

The Process Validation paradigm, when expanded to explicitly include critical definition items as well as important operational and control requirements, is a powerful approach to creating manufacturing capacity to produce high quality product. An understanding of the Quality by Design approach is critical to efficiently developing processes which meet all the complex requirements for supporting a successful manufacturing enterprise. The Validation Lifecycle Matrix (VLM) provides a framework for understanding the complex interactions between Product Development Phases and the four Process Validation Stages required to reach the goal of an efficient and reliable manufacturing enterprise that produces high quality product for the patient population.

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The Year Ahead: New Initiatives to Achieve ISPE's Mission

Berg reviews what's on the horizon in 2013, including surveys, relationship-building, technical study initiatives and new events that will position the Society to become the leading technical organization for professionals engaged in producing quality medicines and pharmaceutical delivery devices throughout the lifecycle.

This is a great time to be a part of ISPE. Not only are ISPE Members leading some of the most sophisticated drug development and production in the history of our industry, they are setting benchmarks for quality and technology that were previously unimaginable. It is a privilege to work with such a distinguished Membership.

In 2013, as part of ISPE's new mission to be the leading technical organization for professionals engaged in producing quality medicines and pharmaceutical delivery devices throughout the lifecycle, we are undertaking a number of new initiatives that include surveys, relationship-building, technical study initiatives and new events. These initiatives will demonstrate the leadership and technical capabilities of the ISPE Membership globally, provide opportunities for involvement by Member segments that are growing or underrepresented, and raise awareness of ISPE among Members, their companies and regulators worldwide. The efforts described below are just a sampling of ISPE work that is intended to help the Society be better positioned to deliver Member value through greater awareness of industry needs and greater involvement in the global regulatory landscape.

One of ISPE's important new initiatives is focused around the very complex and multi-faceted issue of drug shortages. An executive-level ISPE Member team is spearheading development of a survey to determine the root causes of drug shortages; this will help industry and regulators shape a risk-based approach to preventing or alleviating these events. The findings will also help leaders explore whether and how manufacturers could respond to a drug shortage within a short timeframe. This effort has the involvement of the International Leadership Forum (ILF), major companies (including companies that have been involved in some aspect of drug shortages to date), global health authorities including FDA and EMA, as well as associations such as EFPIA, EGA and others. The ISPE survey findings will be presented to FDA for use in responding to the Food and Drug Administration Safety and Innovation Act (FDASIA). This survey will be completed by May of 2013.

In 2013, ISPE will also continue its involvement in discussions and education around the implementation of Quality-by-Design (QbD) and will be working even more closely with regulators in this area. To that end, ISPE will manage a new event focused on the state of QbD being planned for 10-11 April 2013 in San Francisco, CA (USA). Leading the effort are members of the Product Quality Lifecycle Initiative (PQLI), a special interest technical group within the Society.

In 2013, ISPE will also create a number of new technical discussion groups in response to Member and industry input. For example, we will form an exploratory group to discuss Medical Device Security and a new executive forum to discuss Clinical Supply Logistics. We are seeking input from Members interested in these areas -- write to us about potential participation opportunities (nberg@ispe.org). These are two of many new groups that will complement our existing Communities of Practice. It is ISPE's intention to consistently explore evolving areas that serve segments of our Membership that have previously been underrepresented or that could present growth opportunities aligned with ISPE's mission.

All ISPE Members received the 2013 schedule of events postcard in December that highlighted a number of new ISPE conferences. In 2013, ISPE is introducing several "intensive"

events — smaller conferences with more focused technical content. For example, in addition to the QbD event described above, we will host a new Proactive Compliance Conference in New Brunswick, NJ (USA) in October; a Lean Manufacturing Conference in Berlin, Germany, also in October; and we will continue to "Redefine the 'C' in CGMP" at the second ISPE-FDA event this June in Baltimore, MD (USA). If you notice a theme in these programs (hint: quality and best manufacturing practices), you will certainly be interested in the 2-3 April program entitled "Executive Forum: Best Innovation & Quality Practices from Non-Pharma Industries" where experts from the automotive, aerospace and food industries will present some of the most innovative quality and manufacturing processes utilized in their industries to an audience of ISPE delegates. Many other events and meetings are listed on our website at www.ispe.org.

ISPE's mission is focused on being the leading technical association for the industry. Through Member involvement, surveys, programs and networking, we achieve our mission and support the industry in delivering better outcomes for our patient customers. I look forward to your feedback on these or other ISPE initiatives. Even better, if you have an idea for enhancing the value of ISPE, please let me know.

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Report of QbD-Related Regulatory Sessions from ISPE Annual Meeting

by Christopher Potter, PhD, PQLI Technical Project Manager

Introduction

This article summarizes three sessions held 12 to 14 November at the 2012 ISPE Annual Meeting in San Francisco, California, USA, which discussed the current status and challenges for both industry and regulators implementing the science- and risk-based approach to product and process development and introduction into manufacturing. There was an emphasis on application of the enhanced, quality by design (QbD) approach to biotech products. These sessions were:

- Regulatory and Industry Perspectives of QbD
- Process Validation: A Lifecycle Approach with Biotech Applications
- Implementing Pharmaceutical Quality System (PQS) Elements

There are some key themes from these sessions:

- Companies must have a robust Change Management System.
- Information and requests for more flexible regulatory approaches in dossiers should be presented clearly and concisely using consistent ICH nomenclature.
- Further efforts are desired to achieve global harmonization.
- Benefits of using the enhanced, QbD approach have been published, but a wider understanding is required.
- QbD is not just for new products. It can be effectively applied to generics and existing products.
- Examples of use of a lifecycle approach to process validation are emerging.
- Knowledge Management throughout the product lifecycle is very important.

Overview of Regulatory and Industry Perspectives of QbD

Christine Moore, Acting Director, Office of New Drug Quality Assessment, CDER, FDA, USA, said that the number of New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs) with QbD elements is increasing such that FDA may not differentiate "QbD filings." QbD extends to biotech and generic products, and to existing (legacy) products. A joint review exercise with EMA is helping with harmonization, for example, stressing the need for use of ICH terminology; however, further discussion is required on some topics, for example, validation of in-process spectroscopy. Use of clearly justified comparability protocols could lead to increased post approval change flexibility.

> *…the generic industry accepts QbD is the way forward and the benefits can be realized; however, this message needs to be more widely understood.*

Chris Sinko, Senior Vice President, Pharmaceutical Development, Bristol-Myers Squibb, USA, described application of QbD approaches to development of a new drug substance and drug product. Some successes were achieved with approvals for control strategy elements associated with uniformity of dosage units and drug substance impurities. Proposed control strategy elements using particle size to control dissolution were accepted in many countries, but not Japan and the US, both of which requested an algorithm if dissolution was not tested at release.

Yatindra Joshi, Vice President, Generics R&D-US-LATAM, Teva Pharmaceuticals, USA, explained that the generic industry accepts QbD is the way forward and the benefits can be realized; however, this message needs to be more widely understood. A case study applying QbD to a tablet manufactured by dry granulation was presented showing how systematically-designed studies lead to a control strategy with low overall risk of failure. The importance of use of prior knowledge to minimize work was stressed.

Bruce Davis, Principal, Global Consulting, UK, explained how the Product Quality Lifecycle Implementation (PQLI) guide series[1,2] provides practical "how to" guidance on developing products and processes, and implementing in manufacturing. Davis stressed that there are lots of details in the Illustrated Example guide and he presented a summary of a

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...QbD-Related Regulatory Sessions...

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control strategy for drug product containing elements from both drug substance and drug product manufacture.

In the absence of Lawrence Yu, Deputy Director of Science, Office of Generic Drugs (OGD), FDA, Daniel Peng, Senior Staff Fellow, OGD, FDA, said the OGD encourages that QbD principles are applied to the pharmaceutical development of future ANDA product submissions and gave examples of minimum requirements. He also referred to two example ANDA case studies available from the FDA website: one for intermediate release products[3] and one for modified release products.[4] He also explained the importance of continual improvement post approval based on, for example, measures of process capability.

In the Q&A, both Moore and John Lepore, Senior Director, Chemical Process Development and Commercialization, Merck & Co., Inc., USA, explained that proposed design spaces developed based on laboratory scale studies may require different levels of verification at commercial scale depending on the nature of the science. Moore also stressed that movement within design space must be supported by a robust Change Management System (CMS). (Please see reference 5 for guidance on implementing a CMS.) Many members of the panel said that QbD could be applied at relatively low business risk to legacy products and Peng made reference to the PQLI paper, which contains three case studies.[6]

Overview of Process Validation: A Lifecycle Approach with Biotech Applications

Joanne Barrick, Advisor, Global Validation Support, Eli Lilly and Company, USA, summarized ISPE's activities to produce practical guidance to assist in implementation of the FDA's recently issued guidance on process validation.[7] As part of ISPE's PQLI program, two discussion papers have been produced for comment:[8]

1. Determining and Justifying the Number of Process Performance Qualification Batches
2. Applying Continued Process Verification Expectations to New and Existing Products

Jeff Baker, Deputy Director, Office of Biotechnology Products, CDER, FDA, stressed the importance of the lifecycle approach using science and clear justification to support that a product can be made "the same way over and over." He referred to the importance of having a Validation Master Plan,[9] which should summarize the firm's philosophy, intentions, and approach to confirm acceptability of process reproducibility.

Wendy Zwolenski-Lambert, Director, Pharma Business Support, Abbott Laboratories, USA, also emphasized the importance of the lifecycle approach to process validation with the process validation information presented in a submission for a biotech product being an interim milestone. Companies should focus on a "high degree of assurance" of consistent manufacture rather than use statistics or number of batches. Support from laboratory studies is essential and part of the continuum of continued process verification.

Beth Junker, Director, BioProcess Development, Merck & Co., Inc., continued with the same themes as Baker and Zwolenski-Lambert, explaining the importance of knowledge management as an element of process validation. Beth discussed a Merck web-based application based on a risk management template, which is continually updated and is a way of managing knowledge for complex products across complex organizations.

In the Q&A, Junker confirmed that the Merck knowledge management application can be applied to existing products. All panel members confirmed that where there are factors in a process or a control strategy where applicability at scale is not known for certain, a plan is required to verify acceptability at commercial scale.

Overview of Implementing PQS Elements

Rick Friedman, Associate Director, Office of Manufacturing and Product Quality, Office of Compliance, CDER, FDA, stressed that companies cannot outsource responsibility for product quality; the ultimate responsibility always rests with senior management. It is intended that GMPs should support flexibility and continual improvement. Hence FDA's support for ICH Q10, Pharmaceutical Quality System where continual improvements identified from any source, e.g., Corrective Action and Preventative Action (CAPA) or Process Performance and Product Quality Monitoring (PPPQM) systems, can be implemented using a science- and risk-based approach and an effective change management system.

Susan Schebler, Associate Senior Quality Consultant, Eli Lilly and Company, USA, gave a detailed presentation of the ISPE Change Management part of the PQLI® guide series[5] using one of the examples given in the guide.

Lynne Krummen, Senior Director, Genentech, USA, explained that Genentech had achieved significant "flexibility" from FDA compared with previous experiences with two submissions in the FDA's 2009 QbD Biotech Pilot. One was a Biologics License Application (BLA) filed globally, and the other an expanded comparability protocol to support multi-product, multi-site drug substance transfers. The BLA

...QbD-Related Regulatory Sessions...

Continued.

approval achieved reduced testing as part of the control strategy and wider CQA acceptance criteria beyond clinical experience in some cases. Design space proposals were not accepted for a series of good scientific reasons. Differences in judgement of risk between company and FDA were an issue, which a "lessons learned" exercise indicated could be reduced by clear proposals and justifications. The extended comparability protocol did achieve its objectives. Genentech will continue with the QbD approach, learning from these regulatory interactions and recognizing that significant benefits are gained from increased process robustness.

Steve Tyler, Director, Global Quality Systems, Global Pharmaceutical Operations, Abbott Laboratories, USA, discussed – using many examples – the importance to a company of continual improvement and for success, a robust pharmaceutical quality system is required. Tyler showed how analyzing data as part of the application of a PPPQM system identified opportunities for continual improvement and confirmed when improvements had been achieved. He also explained how other measures of product quality, e.g., adverse event monitoring, are important elements of a pharmaceutical quality system, confirming that it is important to consider the totality of product quality measures.

Conclusion

These were three well-attended sessions with lots of learning for participants as well as excellent interaction in the Q&As.

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ISPE Developing Biotechnology Guides

ISPE is currently developing two complementary guides related to biotechnology. The *ISPE Guide: Biopharmaceutical Manufacturing and Process Development* and the *ISPE Guide: Biopharmaceutical Manufacturing Facilities (Second Edition)*. These guides have a distinct but related focus.

Biopharmaceuticals are typically large molecules which may be injected for therapeutic benefit. They are usually heat labile and must be manufactured aseptically. Biopharmaceutical products are also uniquely influenced by their manufacturing process (e.g., cell line or purification methodology).

The manufacture of these products can pose a relatively high risk to patients and close attention needs to be given to the control of manufacturing processes. Technology improvements have resulted in more robust systems that can isolate bioprocess unit operations from the immediate environment. Control of the physicochemical conditions within a process micro-environment is considered more achievable than control of the macro-environment surrounding that process.

The *ISPE Guide: Biopharmaceutical Manufacturing and Process Development* addresses the development, design, and manufacture of biopharmaceutical products. Specifically, it applies to the class of products that include protein therapeutics, monoclonal antibodies, and/or cells or organisms that have been generated or modified by recombinant DNA/RNA, or other technologies to produce APIs. It also includes cell culture based vaccines products. The concepts presented in this Guide can apply to products that are manufactured for clinical trial use, as well as commercial scale production.

Its companion, the *ISPE Guide: Biopharmaceutical Manufacturing Facilities (Second Edition)* applies to facilities housing the development and manufacture of biopharmaceutical drug substances (also known as Bulk Active Pharmaceutical Ingredients (APIs)). The concepts in this Biopharmaceutical Manufacturing Facility Guide support large molecule processing. It evaluates bioprocess unit operations and discusses opportunities for closing these operations; therefore, decoupling them from the environment. Closed processing may represent the lowest risk option in terms of mitigating the risk of environmental contamination. The Guide also considers appropriate facility design attributes that can be used to provide adequate protection of ongoing process unit operations and, ultimately, protection of the manufactured bulk drug substance.

The *ISPE Guide: Biopharmaceutical Manufacturing and Process Development* is in the later stages of development and will be published first, with the Facility Design Guide, which has just completed a review by industry, planned for publication later in the year.

ISPE Guide: Biopharmaceutical Manufacturing and Process Development

The *ISPE Guide: Biopharmaceutical Manufacturing and Process Developmen*t applies to biopharmaceutical products that are regulated by the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER) at the US FDA. It also includes commentary from other countries and regions regarding GMP compliance. National Institutes of Health (NIH) and World Health Organization (WHO) requirements are referenced where applicable.

The guide is intended to be in alignment with ICH Q8 and ICH Q9 and applicable parts of ICH Q10 and ICH Q11, and associated international standards, regulations, and guidance documents.

It is intended that all the guidance offered is compatible as applicable with that in ASTM E2500 Standard for Specifications, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment.

The Guide focuses on process development, approaches, and practices involved in providing regulated, timely, and cost effective manufacturing of biopharmaceutical products that meet their intended use. Scientific and process engineering principles associated with the design, development, optimization, and implementation of processes that are used in manufacturing are considered.

The main objective of this Guide is to provide a roadmap for process development and manufacturing of biopharmaceuticals that provides practical, scientifically sound guidance that helps users incorporate best practices. An important secondary goal of the Guide is to incorporate current regulatory thinking and guidance to increase the efficiency of development activities and to enhance compliance in the development and manufacture of biopharmaceutical products.

This Guide is intended to be used by industry for the design, development and scaling up to regular production, of processes. This guidance provided should be useful to almost anyone involved in these activities, including process development scientists and engineers; manufacturing, quality, and regulatory personnel; along with industry suppliers.

ISPE Guide: Biopharmaceutical Manufacturing Facilities (Second Edition)

The first edition of the Biopharmaceutical Manufacturing Facilities Guide was issued in June 2004. In subsequent years, the concepts developed at that time have been accepted and implemented in a phased approach. One of the main concepts addressed in the first edition began the focus on the

...Biotechnology Guides

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benefits of closed systems. This second edition of the Guide intends to reinforce those concepts further and to take some to the next level. The Guide details the value and benefits of the implementation of closed systems, with examples of how these concepts can be put into practice. The Guide defines what is meant by "closed process" and indicates how closure can be demonstrated through the use of risk assessment tools. Closing a process can improve maintaining product quality and, therefore, improve regulatory compliance. This may even be achieved while reducing some of the environmental restrictions around closed systems. Examples of typical closed processes are given, as well as how some open processes can be made to become closed.

Facilities can be multi-product, requiring short concurrent campaigns and efficient changeover between products; they may be of a reduced scale and increasingly use disposables. This Guide develops concepts to reflect changes in current market demands, new products with more focused patient populations, regulatory conditions, and continued pressures on costs while maintaining high quality standards.

The Guide explains the thinking behind facility layout concepts in relation to facility aspects of product protection and specific requirements of product attributes and production processes.

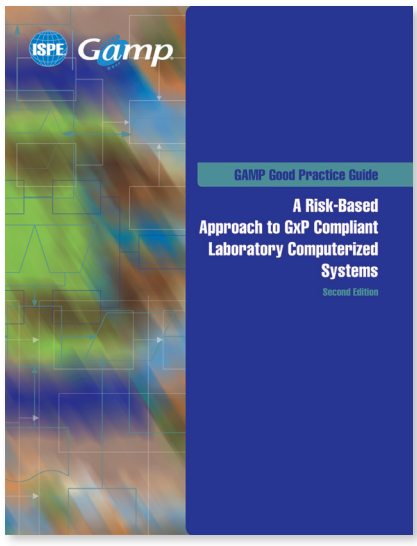
The use of modular concepts (architectural design and construction techniques) allows for faster and less costly projects. Smaller more flexible facilities allow for increased responsiveness to changing product portfolios and market demands. Guidance on architectural and structural aspects of a facility is provided to assist in the initial design implementation process. The Guide also discusses sustainability in the design of biopharmaceutical facilities as a comprehensive approach to the design of facilities that use less resources and energy. Background and links to some of the latest trends in this area and how they affect biotechnology thinking are provided in the Guide.

The Guide also provides typical room criteria and designs. When closed processes are used there is less need for classified spaces. Where open processes are still required, the proper room classification is still needed and the HVAC design must be in place.

The intended audience for the Guide includes professionals involved in the design, construction, qualification, and operation of Biopharmaceutical Drug Substance manufacturing facilities. Regulatory and quality personnel involved in evaluating technical decisions associated with Biopharmaceutical Drug Substance manufacturing plant design are also expected to find the Guide of use.

ISPE Updates Guidance for GxP Compliant Laboratory Computerized Systems

The *ISPE GAMP® Good Practice Guide: A Risk-Based Approach to GxP Compliant Laboratory Computerized Systems (Second Edition)* contains steps that scientists, suppliers and others involved in managing laboratory computerized system acquisition, implementation, and operations can use to verify laboratory computerized systems are fit for their intended use. The Guide provides a practical, risk-based approach, thus eliminating trial and error. Following the principles outlined in the Guide, companies can save time and money, improve communication with external parties and achieve higher quality, better performing systems.



"As the industry continues to focus on solutions to quality issues, the industry's reliance on laboratory computer systems becomes more widespread, and automated laboratory testing and data management operations continue to increase in sophistication and complexity," said Christopher White a member of the team creating this Guide. "At the same time, laboratory personnel typically lack expertise in implementing laboratory systems. This Guide helps them understand the process so they can be effective in this area."

The *ISPE GAMP® Good Practice Guide: A Risk-Based Approach to GxP Compliant Laboratory Computerized Systems (Second Edition)* is available for purchase on the ISPE website at www.ISPE.org/Guidance-Documents.

ISPE Announces 2012 Award Winners at Global Annual Meeting

ISPE announced its 2012 award winners at the Society's Annual Meeting held in San Francisco, California, USA 11 – 14 November. Recognizing the awardees' contributions to ISPE and to the pharmaceutical industry, Nancy S. Berg, President and CEO, presented the honors on behalf of the ISPE Board of Directors.

"As a volunteer organization, ISPE depends on the hearts and minds of its Members and the support of their companies to achieve outcomes that make a difference in terms of industry best practices, product quality and ultimately, patient health," says Berg. "For that reason, recognizing those Members and companies who make contributions that raise the bar for the Society and for the industry is all-important. We are grateful for their work on behalf of ISPE." The 2012 award winners are:

Charles P. Hoiberg, PhD of Pfizer was honored with the ***Joseph X. Phillips Professional Achievement Award***, a special award that recognizes an ISPE Member who has made a significant contribution to the pharmaceutical industry, not just ISPE. Named in honor of Joe Phillips, longtime supporter of ISPE and a leader in establishing the Society as an "integrator" of industry and regulators both during his years of service with the FDA and later when he became International Regulatory Affairs Advisor to ISPE, this award is given infrequently to recognize the extraordinary contributions of its recipients. Hoiberg had a distinguished career at the FDA before joining Pfizer. He has been a member of the International Board of Directors, the ISPE Chair in 2009, chairs ISPE's Regulatory and Compliance Committee, and serves selflessly as a volunteer. He has also served as one of Nancy Berg's advisors throughout her first year as CEO at ISPE.

From left to right: Randy Perez, Past Chair of the ISPE International Board of Directors, Hoiberg, and Charlotte Enghave Fruergaard, 2012-2013 Chair of the ISPE International Board of Directors.

Joanne Barrick of Eli Lilly Company was awarded the ***Max Seales Yonker Member of the Year Award***, which recognizes a Member who has made significant contributions to ISPE in the past 12 months. As a member of the PQLI Technical Committee, the Process Validation Event Planning Committees, an author, adviser, leader and contributor, Barrick has had significant impact on ISPE.

From left to right: Randy Perez, Joanne Barrick, and Charlotte Enghave Fruergaard.

Gert Moelgaard of NNE Pharmaplan was honored with the ***Richard B. Purdy Distinguished Achievement Award***, given in recognition of multiple years of dedicated service to ISPE. Moelgaard has had an impressive career that has had a significant impact on industry and ISPE. He was a founding member of the ISPE Nordic Affiliate, served on the International Board of Directors, was Society Chair in 2006 and has been active on numerous committees including a new role as Co-Chair of the ISPE European Strategy Forum.

The **CGMP Conference Program Committee** and **Young Professionals Committee** were both named ***Committee of the Year***. This award recognizes the

ISPE Announces 2012 Award Winners...

Continued.

From left to right: Randy Perez, Gert Moelgaard, and Charlotte Enghave Fruergaard.

outstanding work of the Society's committees, councils, task teams or community of practice steering committees.

The **CGMP Conference Program Committee** contributed a new experience for ISPE that re-energized the Society and strengthened its position with the FDA. This group worked to produce a major conference in less than four months – a record for ISPE and an admirable accomplishment for any society. ISPE also acknowledges the extraordinary commitment by the FDA in this effort and the leadership of Ilisa Bernstein, Steve Lynn, Rick Friedman, Janet Woodcock, Christine Moore and many others throughout the agency.

cGMP Conference Program Committee

Chair: Brian Lange, PE
Co-Chair: Steven Lynn
Michael A. Arnold, RPh
Robert G. Baum, PhD
James A. Breen, Jr., PE, LEED AP
J. David Doleski
Joseph C. Famulare
Richard L. Friedman
Pamela S. Grant
Brian J. Hasselbalch
Rhonda B. Hill
Charles P. Hoiberg, PhD
Arthur D. Perez, PhD
Michael D. Smedley

The **Young Professionals (YP) Committee** actively engages YP participation throughout the Society; inspired YP participation in Affiliate and Chapter leadership positions; initiated a YP leadership ladder locally (and eventually, internationally) and worked with the Volunteer Services Subcommittee to create a mentorship program for the Society that resulted in greater visibility at colleges, universities, high schools, and even grade schools.

Young Professionals Committee

Chair: Daniel E. Ramsey
Co-Chairs: Amy L. Lineberry, CPIP and Emily Stump
Jamie R. Angelastro
Jane R. Brown
Jennifer L. Clark, CPIP
Tiffany L. Coleman
Blake F. Derrick
Jennifer M. Duffy
William J. Dugary
Russell Early
Wendy T. Haines, PhD
Sarah E. Langan
Robert R. Lechich, CPIP
Joseph J. Manfredi
David A. Mourra

From left to right: Randy Perez, YP Chair Dan Ramsey and Co-Chairs Amy Lineberry, CPIP, and Emily Stump, and Charlotte Enghave Fruergaard.

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ISPE Announces 2012 Award Winners...

Continued from page 91.

From left to right: Randy Perez, Jeff Biskup, CRB President and CEO, and Charlotte Enghave Fruergaard.

Alexander J. Myers
Aarash Navabi
LeAnna M. Pearson
Scott P. Revelli
Roger C. Shillitoe, BSc C Eng FIChemE
Brody J. Stara
Nancy E. Tomoney
Stephen M. Tyler
Ashlee Ujifusa
Michael J. Walters, PhD
Kaitlin E. Worden

From left to right: Randy Perez, Tatsuro Miyagawa, Japan Chair, and Charlotte Enghave Fruergaard.

CRB Consulting Engineers, Inc. was named ***Company of the Year***, an award that honors outstanding support provided by a company as reflected in commitment to the mission of the organization as well as through company employees' significant active participation in the Society's committees, councils, task teams, COPs, programs and activities. CRB is a company that supports the Society in every way from membership to advertising, exhibiting and support. The company has nearly 170 active Members in ISPE and has been a bellwether in the support of our Chapters, Communities of Practice and committees for many years.

From left to right: Randy Perez, Alex Brindle, and Charlotte Enghave Fruergaard.

Alex Brindle, Steven Davy, PhD, David Tiffany and **Chris Watts** were awarded the ***Roger F. Sherwood Article of the Year Award*** for their article, "Risk Analysis Mitigation Matrix (RAMM): A Risk Tool for Quality Management," published in the January/February 2012 issue of *Pharmaceutical Engineering* Magazine.

The **Japan Affiliate** received, for the second year in a row, the ***Affiliate of the Year Award***. This award recognizes the outstanding work of one of ISPE's International Affiliates, as reflected by membership development and services, management, industry and society support and innovation. ISPE Japan has established very high benchmarks in the areas of leadership, membership, retention and events, and this Affiliate does outstanding work to honor the ISPE global brand.

The **University of California, San Diego** received ISPE's ***2012 Student Chapter of the Year Award***, which honors ISPE's top Student Chapter for outstanding

2012 Award Winners...

Continued.

From left to right: Randy Perez, Student Chapter President Yukti Gangwani, San Diego Chapter President Christy Pavano, and Charlotte Enghave Fruergaard.

efforts and hard work managing the Student Chapter.

The ***North American/South American Affiliate Council Chapter Excellence Program*** honors excellence and innovation for ISPE's 16 North American Chapters:

- The **Boston Area Chapter** received the *2012 Platinum Grand Award for Excellence and Innovation*.
- The **San Francisco/Bay Area Chapter** received the ***2012 First Place Award for Excellence and Innovation (Medium Chapter)***.
- The **San Diego Chapter** received the ***2012 First Place Award for Excellence and Innovation (Small Chapter)***.

From left to right: Randy Perez, Brian Hagopian, CPIP, Boston Area Chapter Past President, and Charlotte Enghave Fruergaard.

Concludes on page 94.

ISPE Announces 2012 Award Winners...

Continued from page 93.

From left to right: Randy Perez, Kelly Keen, San Francisco/Bay Area Chapter Past President, and Charlotte Enghave Fruergaard.

From left to right: Randy Perez, Christy Pavano, San Diego Chapter President, and Charlotte Enghave Fruergaard.

Chapter Excellence Awards

- Grand Award for Innovation in Communications: Carolina-South Atlantic Chapter
- First Place Award for Innovation in Communications: Pacific Northwest Chapter
- Grand Award for Innovation in Membership Services: Boston Area Chapter
- Grand Award for Innovation in Programs and Events: Boston Area Chapter
- First Place Award for Innovation in Programs and Events: San Diego Chapter
- Grand Award for Innovation in Student Programs: Carolina-South Atlantic Chapter
- First Place Award for Innovation in Student Programs: San Francisco/Bay Area Chapter

The ***International Student Poster Competition Awards*** honor the top undergraduate and graduate student posters among finalists who won competitions earlier in the year and as selected by judges at the Annual Meeting.

- **Kerri Killen** from Stevens Institute of Technology, New Jersey Chapter was the 2012 Undergraduate winner.
- **Shyamala Pillai** from New Jersey Institute of Technology, New Jersey Chapter, was the 2012 Graduate winner.

From left to right: Randy Perez, Kerri Killen, and Charlotte Enghave Fruergaard.

From left to right: Randy Perez, Shyamala Pillai, and Charlotte Enghave Fruergaard.

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API Manufacturing

Alfa Laval Reactor Technology
AMCOL International
Chemical Transfer Technology Ltd.
Class Biologically Clean Ltd.
Cockram Construction
Dalton Pharma Services
Fareva
Glenmark Generics Ltd.
Hermann WALDNER GmbH & Co. KG
HOSOKAWA ALPINE Aktiengesellschaft
Matcon China
Matcon USA
New Wayz Consulting Ltd.
PharmaCore, Inc.
ProSys Containment & Sampling Technology
Sabin Metal Corporation
Savillex Corporation
Svanholm.com

API Solubilization Technologies

Thermo Scientific - Material Characterization

Academia

Biotechnical Services, Inc.
TTE Laboratories

Accelerated Stability Studies

Cincinnati Sub-Zero

Aerosol Filling

Dynamic Air Quality Solutions

Agglomeration

Fluid Air
Freund-Vector Corporation
Glatt Air Techniques, Inc.
MagnaSafe International
The Fitzpatrick Company

Analytical Equipment

ASCO Numatics
B&W Tek, Inc.
Biotechnical Services, Inc.
Endress+Hauser
enviroflo
Fluid Imaging Technologies, Inc.
GE Analytical Instruments
Hach Company
Mettler-Toledo Thornton, Inc.
MKS Instruments, Inc.
Particle Measuring Systems
Physical Sciences, Inc.
Rigaku Raman Technologies
Shanghai Meiyou Pharmaceutical Co. Ltd.
Shimadzu Scientific Instruments
Svanholm.com
Swagelok
Swan Analytical USA
Thieme Corporation
TSI, Inc.

Analytical Laboratory Services

Azzur Labs, LLC
Accurate Environmental
Actlabs
Biomanufacturing Training and Education Center (BTEC)
Bureau Veritas North America, Inc.
Catalent Pharma Solutions
Ceutical Laboratories, Inc.
Chemical Solutions Ltd.
Chemir - A Division of Evans Analytical Group
EAG Life Sciences
ENV Services, Inc.
Fluid Imaging Technologies, Inc.
International Products Corporation
Microbiology & Quality Associates, Inc.
Q Laboratories, Inc.
Swagelok
Trace Analytics, LLC
University of Iowa Pharmaceuticals

Analytical Methods Development

Actlabs
Avid Bioservices, Inc.
Bureau Veritas North America, Inc.
Ceutical Laboratories, Inc.
Chemical Solutions Ltd.
Dalton Pharma Services
EAG Life Sciences
Frontage Laboratories, Inc.
HealthCore, Inc.
Q Laboratories, Inc.

Analytical Validation Studies

Ceutical Laboratories, Inc.
Chemical Solutions Ltd.
CoreRx, Inc.
EAG Life Sciences
HealthCore, Inc.

Anti-Counterfeiting Technology

AlpVision SA
Compliance Control Ltd.
InfraTrac
Ticona Engineering Polymers
Uhlmann VisioTec GmbH

Architectural Services

CRB
Flad Architects
LifeTek
mitchell architectural group, p.c.
PM Group
Professional Project Services, Inc.
SABArchitects, Inc.

Architecture/Engineering/Construction

NNE Pharmaplan A/S
NNE Pharmaplan sas
AES Clean Technology, Inc.
Amcec, Inc.
Bouchard Consulting Services
Business Horizons
Cascade Scientific, Inc.
CE&IC
Century 3 (Shanghai), Inc.
Clean Rooms West, Inc.
Cleanroom Consulting, LLC
Cleanseal Door Systems - A Division of ASI Technologies
CRB
Hargrove Engineers + Constructors
Hipp Engineering & Consulting, Inc.
HWI Global
IPS-Integrated Project Services
Jacobs/Wyper Architects, LLP
Key Resin Company
LifeTek
M+W Group
M+W Process Industries GmbH
M+W Saudi Arabia Ltd.
M+W Taiwan
M+W Thailand Ltd.
McCarthy Building Companies, Inc.
ModularPartners
MSS Clean Technology Ltd.
Mussett Nicholas and Assoc., Inc.
NEST Consulting
O'Neal, Inc.
Plascore, Inc.
PM Group
Precis Engineering, Inc.
Professional Project Services, Inc.
PROGMP SAS
PS&S, LLC
SABArchitects, Inc.
Seismic Installations, Inc.
Sika Corporation
Skanska
Sweett Group
Talboom PharmaChem NV
Telstar Life Sciences
The Hart Companies
WSP CEL
Zarpac, Inc.

Aseptic Processing

AWS Bio-Pharma Technologies
Adam Fabriwerk Pvt. Ltd.
Agalloco & Associates, Inc.
Bürkert Fluid Control Systems
Bausch + Stroebel
Bausch Advanced Technology Group
BioPharma Systems
Bioquell
Bosch Packaging Technology
Class Biologically Clean Ltd.
DXC Consulting Ltd.
Fareva
Fedegari Autoclavi SpA
GEA Westfalia Separator
Grand River Aseptic Manufacturing, Inc.
IMA Life North America Inc.
Integrated Compliance Solutions, LLC
Jordan Valve
Lighthouse Worldwide Solutions
Pentair Sudmo
PharmaSystems, Inc.
REMCON Plastics
Rompharm Company
Shibuya Hoppmann Corporation
SKAN AG
The Williamsburg Group, LLC
TSI, Inc.
University of Iowa Pharmaceuticals
Vanrx Pharmasystems
Watson-Marlow Pumps Group
Weiler Engineering, Inc.
ZenPure
Zeta Biopharma GmbH

Auditing

Azzur Group, LLC
Advanced Biomedical Consulting (ABC), LLC
Catalyst Pharma Consulting
Compliance Control Ltd.
CTG
David H. Artiss and Associates, Inc.
Document Center, Inc.
GxP Associates
Halfmann Goetsch Partner AG
Infodynamics s.r.l.
Integrated Compliance Solutions, LLC
M+W Process Industries GmbH
Malawer & Associates Consulting, LLC
MasterControl, Inc.
NetDimensions (UK) Limited
NNE Pharmaplan India Limited
NNE Pharmaplan Sdn. Bhd.
Noblitt & Rueland
NSF-DBA
OOO NNE Pharmaplan
Performance Validation
PharmaSys, Inc.
Prime Technologies, Inc.
PROGMP SAS
PSC Biotech
QPharma, Inc.
SeerPharma (Singapore) Pte. Ltd.
The Williamsburg Group, LLC
TRAQuE Pte. Ltd.
US Data Management
VPCI, Inc.

Automated Pharmacology

Banner Engineering Corp

Automation

NNE Pharmaplan A/S
NNE Pharmaplan AB
NNE Pharmaplan Consultoria Ltda.
NNE Pharmaplan GmbH
NNE Pharmaplan, Inc.
NNE Pharmaplan sas
Acquire Automation
AIV Solutions
Applied Control Engineering, Inc.
ASCO Numatics
Astech Projects
Ausenco PSI
Avanceon
Banner Engineering Corp
BatchControl Ltd.
Beamex, Inc.
Broadley-James Ltd.
Bürkert Fluid Control Systems
Burns & McDonnell
Burns Engineering
CrossPoint Engineering
DAI
Dart Controls, Inc.
E2i
em-tec Flow Technology LP
Endress+Hauser
Enhanced Information Solutions (EIS)
Fike
FlexFit Hose
FOSS NIRSystems, Inc.
Freezerworks
GE Analytical Instruments
Getinge Life Science Americas
GSC Engineering, Inc.
Hardy Process Solutions
Harrington Pure
Hazardous Technical Services Ltd.
Huffman Engineering, Inc.
Hyde Engineering + Consulting, Inc.
IPR, Inc.
K-Tron G.B. Ltd.
K-Tron Pitman
K-Tron Salina
Kereon AG
M+W Automation
M+W Group
MagneMotion

MKS Instruments, Inc.
New England Controls, Inc.
NNE Pharmaplan (Tianjin) Co. Ltd.
NZ Controls Ltd.
optek-Danulat, Inc.
Optimation
Pentair Sudmo
Praxair, Inc.
Precia-Molen UK Ltd.
Prime Technologies, Inc.
Process Plus, LLC
Provalidus
QSPEC Solutions, Inc.
RJR Technical Services
seepex, Inc.
Sensor Technology Ltd.
SpecLine Consulting, Inc.
Spirax Sarco
Swagelok
TATNUCK, Inc.
Technical Engineering Ltd.
TiPS Incorporated
Uhlmann VisioTec GmbH
Werum Software & Systems AG
Yokogawa

Bar Coding

Banner Engineering Corp
Control Micro Systems, Inc.
Covan Systems
Freezerworks
GA International, Inc.
Innovatum, Inc.
PRISYM ID
Wayahead Systems

Barrier Isolation

AWS Bio-Pharma Technologies
BioPharma Systems
Bosch Packaging Technology
Chase-Logeman Corporation
Class Biologically Clean, Ltd.
DEC-USA
EnGuard Systems
enviroflo
Extract Technology Ltd.
FPS Food and Pharma Systems
Getinge Life Science Americas
Getinge-La Calhene
IMA Life North America, Inc.
Isolation Systems, Inc.
Lighthouse Worldwide Solutions
M. Braun
ONET Technologies UK Ltd.
PharmaSystems, Inc.
Pharminox Isolation (Cambridge) Ltd.
Powder Systems Ltd. (PSL)
ProSys Containment & Sampling Technology
RPA
Solo Containment
Walker Barrier Systems

Bio-analytical Analysis LC/MS/MS

Frontage Laboratories, Inc.

Bio-analytical Services

Actlabs
Biomanufacturing Training and Education Center (BTEC)
ChanTest Corporation
Warsash Scientific

Bio-processing – Disposable

AlphaBio, Inc.
Colder Products Company
Dow Corning Corporation
G&G Technologies, Inc.
Jeff Smith & Associates, Inc.
Pall Life Sciences
Thermo Fisher Scientific
Value Plastics, a Nordson Company
ZenPure

Biological Testing

Azzur Labs, LLC
Associates of Cape Cod, Inc.
Azbil BioVigilant
Feldmeier Equipment
Microbiology & Quality Associates, Inc.
Perritt Laboratories
Q Laboratories, Inc.
Rapid Micro Biosystems
Skytech Systems (I) Pvt. Ltd.
Technical Safety Services
TRI Air Testing, Inc.
TTE Laboratories

Biologics Manufacturing

Bioproduction Group (BIO-G)
Business Horizons
Dow Corning Corporation
GEA Westfalia Separator
Patheon, Inc.
PharmaBioSource, Inc.
Simplyfeye Softwares (P) Ltd.
WaterSep Technology Corp.

Biologics Process Development

Biomanufacturing Training and Education Center (BTEC)
Bioproduction Group (BIO-G)
M+W Saudi Arabia Ltd.
Thermo Fisher Scientific
WaterSep Technology Corp.
ZenPure

Biometrics

Amarex Clinical Research
Feldmeier Equipment

Biopharmaceuticals/ Biotechnology

Bürkert Fluid Control Systems
NNE Pharmaplan AG
NNE Pharmaplan Sdn. Bhd.
NNE Pharmaplan (Tianjin) Co. Ltd.
Alfa Aesar
Amarex Clinical Research
AMCOL International
Aqua-Chem, Inc.
ASCO Numatics
Associates of Cape Cod, Inc.
Bioproduction Group (BIO-G)
Budzar Industries
ChargePoint Technology
CRANE ChemPharma Flow Solutions
Dyadic International, Inc.
DynPort Vaccine Company LLC, A CSC Company
Feldmeier Equipment
Foster Wheeler
GEA Diessel GmbH
Gemu Valves Limited
ILC Dover
Instalaciones ELUR, S.L.
Lives International
LJ Star, Inc.
M+W Group
M+W Group – Total Facility Solutions, Inc.
M+W Israel Ltd.
M+W Process Industries GmbH
M+W Singapore Pte. Ltd.
Millrock Technology, Inc.
New Wayz Consulting Ltd.
Pall Life Sciences
Physical Sciences, Inc.
Savillex Corporation
Spirax Sarco
Svanholm.com
WaterSep Technology Corp.
Williams Process Ltd.

Bioprocess Manufacturing

Adam Fabriwerk Pvt. Ltd.
Avid Bioservices, Inc.
Banner Engineering Corp
Bioproduction Group (BIO-G)
em-tec Flow Technology LP
Jeff Smith & Associates, Inc.
M+W Group – Total Facility Solutions, Inc.
Pall Life Sciences
Physical Sciences, Inc.
Production Modelling
Simplyfeye Softwares (P) Ltd.
Thermo Fisher Scientific
WaterSep Technology Corp.

Bioprocess Validation

Colder Products Company
M+W Taiwan
PS&S, LLC
Simplyfeye Softwares (P) Ltd.
TRAQuE Pte. Ltd.

Biostatistics

AICOS Technologies Ltd.
Amarex Clinical Research
Business & Decision Life Sciences
HealthCore, Inc.

Blending

Matcon Ltd.
A & M Process Equipment Ltd.
Absolute Handling Systems Ltd.
Benz Technology International, Inc.
CDM
Dart Controls, Inc.
Dec Group
DEC-USA
Fristam Pumps USA
GlobePharma, Inc.
Hardy Process Solutions
K-Tron G.B. Ltd.
Matcon China
Matcon Japan
Matcon USA
Romaco FrymaKoruma
SPX Flow Technology
Sterling, Inc.

Bulk/API

Alfa Aesar
Andreasen & Elmgaard A/S
ChargePoint Technology
K-Tron (Shanghai) Co. Ltd.
Matcon France & Germany
Matcon Ltd.
ProSys Containment & Sampling Technology
CGMP Synthesis
PharmaCore, Inc.

CIP Process Systems

NNE Pharmaplan Consultoria Ltda.
Adam Fabriwerk Pvt. Ltd.
Alfa Laval
APV, An SPX Brand
Aquafine Corporation
Bürkert Fluid Control Systems
Budzar Industries
Dec Group
Electrol Specialties Co.
Environmental Water Systems
Fristam Pumps USA
G&G Technologies, Inc.
HallTech
Hyde Engineering + Consulting, Inc.
Hydro-Thermal Corp
IWT srl
M+W Saudi Arabia Ltd.
McFlusion, Inc.
MKS Instruments, Inc.
Shanghai Ritai Medicine Equipment Project Co. Ltd.

CRO – Clinical or Contract Research

BSSN Software
ChanTest Corporation
Frontage Laboratories, Inc.
Global Research Services, LLC
Kinexus
Vanta Bioscience LC

Calibration/Measurement

Ace Control Systems Ltd.
AOIP SAS
Beamex, Inc.
Biotechnical Services, Inc.
Burns Engineering
Cascade Scientific, Inc.
CrossPoint Engineering
E+E Elektronik Corp.
Endress+Hauser
ENV Services, Inc.
Gemini Data Loggers
GenesisSolutions
HWMR Ltd.
Johnson Controls
Masy Systems, Inc.
Meriam Process Technologies
Mettler-Toledo Thornton, Inc.
Micro-Clean, Inc.
Microbiology & Quality Associates, Inc.
Optimation
Prime Technologies, Inc.
PS&S, LLC
RPA
Sensor Technology Ltd.
Skytech Systems (I) Pvt. Ltd.
Technical Safety Services
TESTO, Inc.

Central Lab Services

Johnson Controls

Chemical Analysis

Actlabs
Chemir - A Division of Evans Analytical Group
EAG Life Sciences
Kahle Automation

Mettler-Toledo Thornton, Inc.
Polymer Solutions
Rigaku Raman Technologies
TTE Laboratories
Warsash Scientific

Chemical Cleaning

Allegheny Surface Technology
Ateco Services AG
McFlusion Corp
STERIS Life Sciences
The Hart Companies

Chemicals/Reagents/ Standards

Alfa Aesar
Qorpak

Clean In Place/Sterilization In Place (CIP/SIP)

American Plastic Technologies, Inc.
ARS/Beverly Pacific Sterilizers
Bioquell
Colder Products Company
Endress+Hauser
Environmental Water Systems
Fike
FlexFit Hose
Fristam Pumps USA
GEA Lyophil GmbH
GESTRA AG
Getinge Life Science Americas
HallTech
Hyde Engineering + Consulting, Inc.
Hydro-Thermal Corp
IN USA, Inc.
IWT srl
Jordan Valve
M+W Group – Total Facility Solutions, Inc.
McFlusion, Inc.
PSC Asia
Sixlog
Spraying Systems Co.
Telstar
WCB, An SPX Brand

Clean Room Equipment and Supplies

gammaSUPPLIES
Instalaciones ELUR, S.L.
International Products Corporation
Isolation Systems, Inc.
Mar Cor Purification
Micro-Clean, Inc.
Microzone Corporation
Nextteq, LLC
Q Applied Systems, Corp.
Remco Products Corporation
Solo Containment
Spirax Sarco

Clean Room Services

NNE Pharmaplan A/S
AES Clean Technology, Inc.
Airy Filtration Co. Ltd.
Astro Pak
Camfil Farr
Clean Rooms West, Inc.
Cleanroom Consulting, LLC
Cleanroom Solutions Ltd.
Controlled Contamination Services
ENV Services, Inc.
Filter Sales & Service
Filter Technologies, Inc.
HWI Global
Instalaciones ELUR, S.L.
M+W Israel Ltd.
M+W Saudi Arabia Ltd.
M+W Taiwan
Microzone Corporation
Milholland & Associates
MSS Clean Technology Ltd.
NEST Consulting

Cleaning/Cleaning Validation

PSC Biotech
Validation, Inc.
Alfa Laval Tank Equipment
Allegheny Surface Technology
Andreasen & Elmgaard A/S
Ateco Services AG
Belimed, Inc.
Bioquell, Inc.
Controlled Contamination Services
GlobePharma, Inc.
HallTech
HWI Global
Hyde Engineering + Consulting, Inc.
IN USA, Inc.
International Products Corporation
IWT srl
McFlusion, Inc.
McGee Pharma International
Performance Validation
ProPharma Group
Rozembersky Group, Inc.

Clinical Monitoring

Amarex Clinical Research
Elpro Services, Inc.
Global Research Services, LLC

Clinical Supply Management

Catalent Pharma Solutions
Clinigen CTS
Creapharm
Sharp Clinical Services

Clinical Trials Management

Amarex Clinical Research
AMEDON GmbH
ARX
Business & Decision Life Sciences
Freezerworks
Frontage Laboratories, Inc.
Global Research Services, LLC
Innovatum, Inc.
Werum Software & Systems AG

Clinical/Investigational Products

Clinigen CTS
Emerson Resources, Inc.

Cold Chain

AndersonBrecon
BioConvergence, LLC
Creapharm
Elpro Services, Inc.
Gemini Data Loggers
HWMR Ltd.
Intelleflex
Praxair, Inc.
Sensitech, Inc.
Thermal Compliance Ltd.
Vaisala

Cold Chain Management

BioConvergence, LLC
Creapharm
HWMR Ltd.
Intelleflex
Praxair, Inc.
Sensitech, Inc.

Commercial Drug Sourcing

Clinigen CTS
Creapharm
Sharp Clinical Services

Commissioning and Qualification

CAI (Shanghai) Engineering Consulting Co. Ltd.
Commissioning Agents International
Commissioning Agents International Singapore Pte. Ltd.
Commissioning Agents Ireland Ltd.
Commissioning Agents Puerto Rico, LLC
Commissioning Agents, Inc.
Nivasoft, Inc.
PharmaSys, Inc.
SpecLine Consulting, Inc.

Computer Services

Azzur Group, LLC
CQV (CimQuest Vantage)
andesys international corp.
BatchControl Ltd.
BSSN Software
Business & Decision Life Sciences
Compliance Control Ltd.
CTG (UK) Limited
Enhanced Information Solutions (EIS)
Nivasoft, Inc.
OctaveSoft GmbH
PleaseTech Ltd.

Construction Services Contractor

Clean Rooms West, Inc.
Cockram Construction
Dome Construction
Fraser Engineering, Inc.
GMP Piping, Inc.
HWI Global
M+W Group
M+W Group – Total Facility Solutions, Inc.
M+W Process Industries GmbH
M+W Thailand Ltd.
McCarthy Building Companies, Inc.
MSS Clean Technology Ltd.

Construction Services/ Management

NNE Pharmaplan GmbH
AllianzOne Private Limited
Burns & McDonnell
Century 3 (Shanghai), Inc.
Cockram Construction
CRB
Dome Construction
Fraser Engineering, Inc.
Hipp Engineering & Consulting, Inc.
HOCHTIEF Solutions AG
International Coatings
IPS-Integrated Project Services
M+W Group
M+W Process Industries GmbH
M+W Taiwan
M+W Thailand Ltd.
McCarthy Building Companies, Inc.
ModularPartners
O'Neal, Inc.
PS&S, LLC

Consulting – Audits and Inspections

CAI (Shanghai) Engineering Consulting Co. Ltd.
Commissioning Agents International
Commissioning Agents International Singapore Pte. Ltd.
Commissioning Agents Ireland Ltd.
Commissioning Agents Puerto Rico, LLC
Commissioning Agents, Inc.
MIVADO GlobalPerformance, Inc.
PharmaSys, Inc.
US Data Management

Consulting – Health Safety and Environment (HSE)

PS&S, LLC

Consulting – Process Analytical Technology (PAT)

CAI (Shanghai) Engineering Consulting Co. Ltd.
Commissioning Agents International
Commissioning Agents International Singapore Pte. Ltd.
Commissioning Agents Ireland Ltd.
Commissioning Agents Puerto Rico, LLC
Commissioning Agents, Inc.
Malawer & Associates Consulting, LLC
Tunnell Consulting, Inc.
Uhlmann VisioTec GmbH
Zarpac, Inc.

Consulting – Process Excellence

CAI (Shanghai) Engineering Consulting Co. Ltd.
Commissioning Agents International
Commissioning Agents International Singapore Pte. Ltd.
Commissioning Agents Ireland Ltd.
Commissioning Agents Puerto Rico, LLC
Commissioning Agents, Inc.
ABB Control Technologies
Acquire Automation
Changeover.com
Halfmann Goetsch Partner AG
Maxiom Group
QSPEC Solutions, Inc.
STEXCON
Tunnell Consulting, Inc.
Zarpac, Inc.

Consulting – Quality Management Systems

CAI (Shanghai) Engineering Consulting Co. Ltd.
Commissioning Agents International
Commissioning Agents International Singapore Pte. Ltd.
Commissioning Agents Ireland Ltd.
Commissioning Agents Puerto Rico, LLC
Commissioning Agents, Inc.
CQV (CimQuest Vantage)
AL Engineering
andesys international corp.
Compliance Control Ltd.
CTG (UK) Limited
Deloitte
DynaGMP
DynPort Vaccine Company LLC, A CSC Company
Enhanced Information Solutions (EIS)
GE Analytical Instruments
Halfmann Goetsch Partner AG
Malawer & Associates Consulting, LLC
MasterControl, Inc.
Maxiom Group
McGee Pharma International
MIVADO GlobalPerformance, Inc.
Nivasoft, Inc.
Parsec Automation
Performance Validation
PharmaConsult Us, Inc.
Protocol Link, Inc.
Rescop BV
SeerPharma (Singapore) Pte. Ltd.
Semcon (Beijing) Information & Consulting Co. Ltd.
TRAQuE Pte. Ltd.
US Data Management
Vaisala

Consulting – Records Management

CQV (CimQuest Vantage)
Document Center, Inc.
DynaGMP
EMSI
Noblitt & Rueland
Recordsforce, Inc.

Consulting – Regulatory

PSC Biotech
Catalyst Pharma Consulting
Ceutical Laboratories, Inc.
DXC Consulting Ltd.
DynPort Vaccine Company LLC, A CSC Company
EMSI
Frontage Laboratories, Inc.
HealthCore, Inc.
Infodynamics s.r.l.
MasterControl, Inc.
MIVADO GlobalPerformance, Inc.
Pharma Insight, Inc.
PharmaSys, Inc.
Protocol Link, Inc.
Specialty Operations Solutions, Inc.
Tunnell Consulting, Inc.
VPCI, Inc.

Consulting – Six Sigma

Bouchard Consulting Services
GenesisSolutions
Kelly Engineering Resources
Maxiom Group
Pharma Insight, Inc.
Zarpac, Inc.

Consulting Services

NNE Pharmaplan A/S
NNE Pharmaplan AB
NNE Pharmaplan AG
NNE Pharmaplan GmbH
NNE Pharmaplan, Inc.
NNE Pharmaplan NV
Advanced Biomedical Consulting (ABC), LLC
Agalloco & Associates, Inc.
AICOS Technologies Ltd.
AllianzOne Private Limited
American Plastic Technologies, Inc.
Andreasen & Elmgaard A/S
arnoult.org
Benz Technology International, Inc.
Bouchard Consulting Services
BSSN Software
Bürkert Fluid Control Systems
Business & Decision Life Sciences
Cleanroom Consulting, LLC
Cockram Construction
CRB
DAI
David H. Artiss and Associates, Inc.
DME Alliance Engineering Consultants
DynaGMP
DynPort Vaccine Company LLC, A CSC Company
Empowerment Quality Engineering Ltd.
Enhanced Information Solutions (EIS)
Hazardous Technical Services Ltd.
Hipp Engineering & Consulting, Inc.
IPS-Integrated Project Services
Kelly Engineering Resources
Kelly Services
LifeTek
M+W Automation
M+W Group
M+W Process Industries GmbH
M+W Singapore Pte. Ltd.
MAM Pharma Engineering Consultants
Maxiom Group
McGee Pharma International
Michelle Marketing
ModularPartners
MSS Clean Technology Ltd.
Multisorb Technologies
NEST Consulting
NSF-DBA
ONET Technologies UK Ltd.
PharmaBioSource, Inc.
Pharmatech Associates, Inc.
Pharminox Isolation (Cambridge) Ltd.
Polymer Solutions
Professional Project Services, Inc.
PROGMP SAS
ProPharma Group
Protocol Link, Inc.
Redline PdM
Rozembersky Group, Inc.
Semcon (Beijing) Information & Consulting Co. Ltd.
SpecLine Consulting, Inc.
Strong Plastics Engineering, Inc.
TalentWRx Life Sciences Staffing
Techceuticals
Techniserv, Inc.
Telstar Life Sciences
The Williamsburg Group, LLC
TiPS Incorporated
Tunnell Consulting, Inc.
Validation Technologies, Inc.
ValSource, LLC
Williams Process Ltd.

Container Testing

ATC Inc. - Advanced Test Concepts, Inc.
Nikka Densok USA, Inc.
ZebraSci, Inc.

Containment

ChargePoint Technology
AFC Air Filtration & Containment GmbH
Affygility Solutions
BioPharma Systems
Bureau Veritas North America, Inc.
Camfil Farr Air Pollution Control
CDM
Class Biologically Clean Ltd.
Contained Technologies, LLC
Dec Group
DEC-USA
Donaldson Torit
Dycem Ltd.
enviroflo
Extract Technology Ltd.
Federal Equipment Company
Filter Sales & Service
Flad Architects
Floura, LLC
FPS Food and Pharma Systems
GEA Lyophil GmbH
GEA Pharma Systems
Gerteis Maschinen + Processengineering AG
Getinge-La Calhene
Hermann WALDNER GmbH & Co. KG
HOSOKAWA ALPINE Aktiengesellschaft
ILC Dover
Isolation Systems, Inc.
Jacobs/Wyper Architects, LLP
M. Braun
Matcon France & Germany
Matcon Japan
Matcon USA
Microzone Corporation
ONET Technologies UK Ltd.
PharmaConsult Us, Inc.
Pharminox Isolation (Cambridge) Ltd.
Powder Systems Ltd (PSL)
ProSys Containment & Sampling Technology
Russell Finex, Inc.
seepex, Inc.
Sepratech International
Shickel Corporation
Sixlog
SKAN AG
Solo Containment
Stevens Pharmaceutical Equipment Industries
Telstar
Telstar Life Sciences
Telstar North America, Inc.
University of Iowa Pharmaceuticals
Walker Barrier Systems

Contaminant Analysis

Chemir - A Division of Evans Analytical Group
Floura, LLC
PharmaConsult Us, Inc.
Sixlog
ZebraSci, Inc.

Contract Development and Manufacturing Organization (CDMO)

Vetter Pharma International GmbH
Avid Bioservices, Inc.
Patheon, Inc.

Contract Manufacturing

AAIPharma
Aqua-Chem, Inc.
Catalyst Pharma Consulting
Christy Pavano Consulting
CoreRx, Inc.
Deerland Enzymes
Fareva
New Life Resources, Inc.
Patheon, Inc.
Plainfield Precision
Rompharm Company
Tapemark
Vetter Pharma International GmbH
Watson-Marlow Pumps Group

Contract Packaging

A+ Secure Packaging
AAIPharma
AndersonBrecon
Creapharm
Fareva
Strong Plastics Engineering, Inc.
Vetter Pharma International GmbH
XERIMIS, Inc.

Contract Research

AAIPharma
BSSN Software
ChanTest Corporation
CoreRx, Inc.
Dyadic International, Inc.
Frontage Laboratories, Inc.
Global Research Services, LLC
Kinexus
PharmaCore, Inc.
Vanta Bioscience LC

Contracting Services

AAIPharma
Associates of Cape Cod, Inc.
Astro Pak
Deerland Enzymes
Kelly Engineering Resources
McCarthy Building Companies, Inc.
Millrock Technology, Inc.

Custom Fabricators

AdvantaPure
Apache Stainless Equipment Corp.
Behringer Corporation
BioPharma Systems
Burt Process Equipment, Inc.
Custom Powder Systems
DCI, Inc.
Electrol Specialties Co.
Enerquip, LLC
Exigo Manufacturing
Fraser Engineering, Inc.
G&G Technologies, Inc.
Garvey Corporation
GMP Piping, Inc.
Integrated Containment Systems
Isolation Systems, Inc.
Shickel Corporation
Techniserv, Inc.
VNE Corporation
Wintek Corporation

Custom Manufacturing
Apache Stainless Equipment Corp.
Aqua-Chem, Inc.
Brevetti Angela S.R.L.
Camfil Farr
Ceramaret SA
Control Micro Systems, Inc.
Deerland Enzymes
Degage Corp.
Donaldson Torit
Epitomics, Inc.
Fab-Tech, Inc.
Fike
Filamatic
Fluid Air
Hydro-Thermal Corp
Integrated Containment Systems
NJM Packaging
Plainfield Precision
Rompharm Company
Savillex Corporation
Spraying Systems Co.
Strong Plastics Engineering, Inc.
Symetix
Thieme Corporation
VNE Corporation
ZenPure

Custom Synthesis
Alfa Aesar
Catalyst Pharma Consulting
Chemir - A Division of Evans Analytical Group
PharmaCore, Inc.

DMF Establishment/ Maintenance
Protocol Link, Inc.

Data Management
arnoult.org
ARX
Ashvins Group, Inc.
Blue Mountain Quality Resources, Inc.
BSSN Software
EMSI
Global Research Services, LLC
KVS Technologies
M+W Automation
New England Controls, Inc.
OctaveSoft GmbH
PleaseTech Ltd.
Recordsforce, Inc.
Rescop BV
Simplyfeye Softwares (P) Ltd.
Tergene Biotech
TiPS Incorporated
Werum Software & Systems AG

Database Systems
AMEDON GmbH
Blue Mountain Quality Resources, Inc.
Freezerworks
OctaveSoft GmbH

Disinfectants
Ateco Services AG
Bioquell, Inc.
By Dezign Products
Hanovia
IN USA, Inc.
Mar Cor Purification
Sixlog

Disposable Device Development and Manufacturing
Value Plastics, a Nordson Company

Disposables
AdvantaPure
AllPure Technologies, Inc.
AlphaBio, Inc.
Broadley-James Ltd.
By Dezign Products
CDM
Colder Products Company
Contained Technologies, LLC
Dow Corning Corporation
Dynarex Corporation
Gemu Valves
Saint-Gobain Performance Plastics
Thermo Fisher Scientific

Distillation
APV, An SPX Brand
Buss-SMS-Canzler GmbH
GMP SYSTEMS LTDA.
LCI Corporation
Pope Scientific, Inc.

Distribution – Clinical Trials
AndersonBrecon
Clinigen CTS
XERIMIS, Inc.

Distribution – Commercial
Camber Pharmaceuticals

Documentation Support Services
CrossPoint Engineering
ETC Sterilization Systems
KVS Technologies
MasterControl Inc.
PleaseTech Ltd.
Recordsforce, Inc.
ValSource, LLC

Dosage Form Development
Dalton Pharma Services
Emerson Resources, Inc.
Huxley Bertram

Downstream Processing
Broadley-James Ltd.
Camfil Farr Air Pollution Control
Jeff Smith & Associates, Inc.
optek-Danulat, Inc.
Pall Life Sciences
WaterSep Technology Corp.

Drug Delivery Systems
Astech Projects
Catalent Pharma Solutions
Laserage
Strong Plastics Engineering, Inc.

Drug Development Services
Catalent Pharma Solutions
Emerson Resources, Inc.
Patheon, Inc.
Vanta Bioscience LC
Vetter Pharma International GmbH

Drug Discovery
Kinexus

Drug Screening
ChanTest Corporation
Shanghai Roche Pharmaceuticals Ltd.
Warsash Scientific
ZebraSci, Inc.

E-Pedigree
Acquire Automation
InfraTrac
Innovatum, Inc.
Intelleflex
Maxiom Group

Electronic Data Capture
AOIP SAS
Lives International
OctaveSoft GmbH
Recordsforce, Inc.

Electronic Data Management
arnoult.org
ARX
Ashvins Group, Inc.
Blue Mountain Quality Resources, Inc.
KVS Technologies
OctaveSoft GmbH
PleaseTech Ltd.
Recordsforce, Inc.
Rescop BV
Werum Software & Systems AG

Engineering and Design Services
NNE Pharmaplan (Tianjin) Co. Ltd.
OOO NNE Pharmaplan
Alden
Ausenco PSI
DME Alliance Engineering Consultants
Key Resin Company
M+W Group
M+W Singapore Pte. Ltd.
Mussett Nicholas and Assoc., Inc.
Techniserv, Inc.

Engineering/Architecture
NNE Pharmaplan GmbH
NNE Pharmaplan, Inc.
NNE Pharmaplan India Limited
Burns & McDonnell
CE&IC
DME Alliance Engineering Consultants
Energy Engineering Co. Ltd.
Hofmeister Engineering, PC
International Coatings
IPS-Integrated Project Services
M+W Group
M+W Israel Ltd.
M+W Process Industries GmbH
NEST Consulting
Nicos Group, Inc.
O'Neal, Inc.
PM Group
Precis Engineering, Inc.

Enterprise Resource Planning
Production Modelling

Environmental Analysis
Azzur Labs, LLC
TSI, Inc.
Accurate Environmental
AOIP SAS
EMSI
Lighthouse Worldwide Solutions
Q Laboratories, Inc.
Technical Safety Services
Warsash Scientific

Equipment/Components
AGRU Kunststofftechnik GmbH
Alfa Laval
Alfa Laval Reactor Technology
Alfa Laval Tank Equipment
Anguil Environmental Systems, Inc.
Atlas Copco Compressors
Benz Technology International, Inc.
Buchi Pilot Plant & Reactors Systems
Buffalo Air Handling
Burns Engineering
Custom Powder Systems
Donaldson Torit
E+E Elektronik Corp.
em-tec Flow Technology, LP
G&G Technologies, Inc.
Garvey Corporation
GMP SYSTEMS LTDA.
GMP Systems, Inc.
Hardy Process Solutions
HEMCO Corporation
Jung Gummitechnik GmbH
K-Tron G.B. Ltd.
LCI Corporation
LJ Star, Inc.
Michelle Marketing
Nextteq, LLC
Nikka Densok USA, Inc.
Qualicaps
Robbins & Myers Process Solutions Group
Sepratech International
Shanghai Ritai Medicine Equipment Project Co. Ltd.
Spirax Sarco Ltd.
Techceuticals
Technical Engineering Ltd.
Wintek Corporation

European QP
Clinigen CTS

Facilities Design
NNE Pharmaplan India Limited
Airy Filtration Co. Ltd.
AllianzOne Private Limited
AWS Bio-Pharma Technologies
Business Horizons
Catalyst Pharma Consulting
CE&IC
Cleanroom Consulting, LLC
Cleanseal Door Systems - A Division of ASI Technologies
DME Alliance Engineering Consultants
Flad Architects
Hipp Engineering & Consulting, Inc.
Hofmeister Engineering, PC
Jacobs/Wyper Architects, LLP

Key Resin Company
LifeTek
M+W Group
M+W High Tech Projects Philippines, Inc.
M+W Process Industries GmbH
Manrochem Limited
McGee Pharma International
Microzone Corporation
mitchell architectural group, p.c.
ModularPartners
Mussett Nicholas and Assoc., Inc.
nora systems, Inc.
North Shore Mechanical Contractors, Inc.
Pharmatech Associates, Inc.
PM Greene Engineers
PM Group
Process Plus, LLC
Professional Project Services, Inc.
SABArchitects, Inc.
Talboom PharmaChem NV
VPCI, Inc.
WSP CEL

Facility Construction

NNE Pharmaplan Consultoria Ltda.
NNE Pharmaplan NV
AES Clean Technology, Inc.
Foster Wheeler
GMP Piping, Inc.
International Coatings
M+W Singapore Pte. Ltd.
M+W Thailand Ltd.
McCarthy Building Companies, Inc.
ModularPartners
nora systems, Inc.
North Shore Mechanical Contractors, Inc.
O'Neal, Inc.
Seismic Installations, Inc.
Skanska
Stonhard
WSP CEL

Facility Engineering and Maintenance

Azzur Group, LLC
Ace Control Systems Ltd.
Airy Filtration Co. Ltd.
Amcec, Inc.
Avanceon
Dart Controls, Inc.
Energy Engineering Co. Ltd.
Fraser Engineering, Inc.
GenesisSolutions
GMP Templates
HOCHTIEF Solutions AG
Hofmeister Engineering, PC
Instalaciones ELUR, S.L.
International Coatings
Kelly Engineering Resources
Key Resin Company
M+W Group – Total Facility Solutions, Inc.
North Shore Mechanical Contractors, Inc.
Precis Engineering, Inc.
Production Modelling
Professional Project Services, Inc.
Redline PdM
Rogers Machinery Co., Inc.
Skanska
Spirax Sarco
TATNUCK , Inc.
TTE Laboratories

Facility Management Services

Business Horizons
Energy Engineering Co. Ltd.
HOCHTIEF Solutions AG
Johnson Controls
M+W Group
Skanska
The Mundy Companies

Facility Planning

Airy Filtration Co. Ltd.
AllianzOne Private Limited
Flad Architects
Hofmeister Engineering, PC
Lighthouse Worldwide Solutions
mitchell architectural group, p.c.
QSPEC Solutions, Inc.

Feasibility Studies

Ausenco PSI
Burns & McDonnell
Foster Wheeler
Manrochem Limited
McFlusion, Inc.
mitchell architectural group, p.c.
Mussett Nicholas and Assoc., Inc.
Sweett Group
Williams Process Ltd.

Fermentation

Biomanufacturing Training and Education Center (BTEC)
Broadley-James Ltd.
Brooks Instrument
Dyadic International, Inc.
Hermann WALDNER GmbH & Co. KG
Luthra Industrial Engineering Corporation
Sartorius Stedim Biotech
Shanghai Ritai Medicine Equipment Project Co. Ltd.
Svanholm.com

Filling

Bausch + Stroebel
BellatRx, Inc.
BioPharma Systems
Bioquell
Bosch Packaging Technology
Brevetti Angela S.R.L.
Brinda Pharma Technologies
Capmatic Ltd.
Chase-Logeman Corporation
Cozzoli Machine Company
Dynamic Air Quality Solutions
enviroflo
Filamatic
Gemu Valves
GMP SYSTEMS LTDA.
Grand River Aseptic Manufacturing, Inc.
groninger USA L.L.C.
IMA Life North America, Inc.
ITCM
Kirby Lester
Lyophilization Technology, Inc.
M&O Perry Industries, Inc.
NJM Packaging
Optima pharma
OPTIMA pharma GmbH
PallayPack
PharmaSystems, Inc.
Rommelag USA, Inc.
Shibuya Hoppmann Corporation
SKAN AG
Vanrx Pharmasystems

Filtration Equipment and Supplies

Camfil Farr Air Pollution Control
Benz Technology International, Inc.
International Products Corporation
Mar Cor Purification
Meissner Filtration Products, Inc.
Mott Corporation
Q Applied Systems Corp.
Qorpak
Sepratech International
SPX Flow Technology

Filtration Services

AFC Air Filtration & Containment GmbH
Camfil Farr Air Pollution Control
Camfil Farr Australia Pty. Ltd.
Filter Technologies, Inc.
Meissner Filtration Products, Inc.
Rozembersky Group, Inc.

Filtration Testing and Certification

Micro-Clean, Inc.

GAMP

AIV Solutions
andesys international corp.
BatchControl Ltd.
CTG (UK) Limited
DAI
Deloitte
GE Measurement & Control
Halfmann Goetsch Partner AG
Kereon AG
KVS Technologies
Provalidus
RJR Technical Services
TATNUCK, Inc.

GLP Auditing

NetDimensions (UK) Limited

GMP Auditing

NNE Pharmaplan India Limited
NNE Pharmaplan Sdn. Bhd.
OOO NNE Pharmaplan
PSC Biotech
David H. Artiss and Associates, Inc.
GxP Associates
Halfmann Goetsch Partner AG
Integrated Compliance Solutions, LLC
M+W Process Industries GmbH
Malawer & Associates Consulting, LLC
NetDimensions (UK) Limited
Noblitt & Rueland
PharmaSys, Inc.
PROGMP SAS
US Data Management
VPCI, Inc.

GMPs

NNE Pharmaplan NV
NNE Pharmaplan sas
Deerland Enzymes
Empowerment Quality Engineering Ltd.

GMP Templates

SeerPharma (Singapore) Pte. Ltd.
Semcon (Beijing) Information & Consulting Co. Ltd.

Genomic/Proteomic

Kinexus

Genomics and Screening

Dyadic International, Inc.

HVAC

Ace Control Systems Ltd.
Buffalo Air Handling
Camfil Farr Australia Pty. Ltd.
Clean Rooms West, Inc.
Energy Engineering Co. Ltd.

Filter Sales & Service

GESTRA AG
Instalaciones ELUR, S.L.
Johnson Controls
Munters Corporation
Q Applied Systems, Corp.
RPA
Somar Engenharia Ltda.
TESTO, Inc.

Health/Safety/Environmental

Affygility Solutions
Amcec, Inc.
By Dezign Products
Contained Technologies, LLC
Fike
Jung Gummitechnik GmbH
Nextteq, LLC
PharmaConsult Us, Inc.
Solo Containment
Williams Process Ltd.

High Throughput Screening

ChanTest Corporation

IT – Clinical Trials Management

AMEDON GmbH
ARX
Freezerworks
Innovatum, Inc.

IT – Data Collection

AMEDON GmbH
Bioproduction Group (BIO-G)
E2i
OctaveSoft GmbH
Parsec Automation

IT – LIMS

CQV (CimQuest Vantage)
ARX
Freezerworks

IT – Outsourcing Services

CQV (CimQuest Vantage)
Ashvins Group, Inc.
Empowerment Quality Engineering Ltd.

IT – Process Automation

NNE Pharmaplan, Inc.
Avanceon
DAI
Enhanced Information Solutions (EIS)
GE Analytical Instruments
Kereon AG
NZ Controls Ltd.
Optimation
Werum Software & Systems AG
Yokogawa

Image Analysis and Microscopy

MNEMONICS, Inc.
Okolab: Live Cell Microscopy

Imaging

MNEMONICS, Inc.
ZebraSci, Inc.

Information Technology

AICOS Technologies Ltd.
arnoult.org
ARX
DAI
Deloitte
Nivasoft, Inc.
PleaseTech Ltd.
Production Modelling

Instruments and Controls

Ace Control Systems Ltd.
Alfa Laval Tank Equipment
Anderson Instrument Company, Inc.
AOIP SAS
Ashcroft, Inc.
ATC Inc. - Advanced Test Concepts, Inc.
Ausenco PSI
Bürkert Fluid Control Systems
BatchControl Ltd.
Beamex, Inc.
Brookfield Engineering Laboratories, Inc.
Brooks Instrument
Burns Engineering
E+E Elektronik Corp.
Endress+Hauser
Gemini Data Loggers
Gemu Valves
Hach Company
Hazardous Technical Services Ltd.
Huffman Engineering, Inc.
HWMR Ltd.
Meriam Process Technologies
MKS Instruments, Inc.
Okolab: Live Cell Microscopy
optek-Danulat, Inc.
Particle Measuring Systems
Swan Analytical USA
TSI, Inc.
Vaisala
Yokogawa

Investigational Products

Clinigen CTS
Emerson Resources, Inc.
Integrated Compliance Solutions, LLC

Laboratory Equipment

A & M Process Equipment Ltd.
ARS/Beverly Pacific Sterilizers
Bahnson Environmental Specialties, LLC
Belimed, Inc.
Bioquell, Inc.
Buchi Pilot Plant & Reactors Systems
Burns Engineering
Buss-SMS-Canzler GmbH
Dagard Clean Room
DJS Enterprises
em-tec Flow Technology, LP
enviroflo
ETA Process Instrumentation
Exergy, LLC
Fab-Tech, Inc.
Fedegari Autoclavi SpA
Filamatic
FOSS NIRSystems, Inc.
Freund-Vector Corporation
Gemini Data Loggers
Getinge-La Calhene
Harrington Pure
HEMCO Corporation
Huxley Bertram
Kirby Lester
MagnaSafe International
Mar Cor Purification
Microzone Corporation
Nikka Densok USA, Inc.
Okolab: Live Cell Microscopy
PharmaSystems, Inc.
Pharmatron, Inc.
Q Applied Systems Corp.
Q-Lab Corporation
Russell Finex, Inc.
Safety Emporium
Shanghai Ritai Medicine Equipment Project Co. Ltd.
Shimadzu Scientific Instruments
Skytech Systems (I) Pvt. Ltd.
STERIS Life Sciences
Thieme Corporation
Watson-Marlow Pumps Group

Laboratory Facility Design

Century 3 (Shanghai), Inc.
Cleanroom Solutions Ltd.
Dagard Clean Room
Flad Architects
HEMCO Corporation
Jacobs/Wyper Architects, LLP
mitchell architectural group, p.c.
Mussett Nicholas and Assoc., Inc.
nora systems, Inc.
SABArchitects, Inc.
The Hart Companies

Laboratory Operations

Biotechnical Services, Inc.
Specialty Operations Solutions, Inc.

Laboratory Supplies

Accurate Environmental
Berkshire
Brinda Pharma Technologies
GA International, Inc.
gammaSUPPLIES
International Products Corporation
Nextteq, LLC
Q Applied Systems Corp.
Qorpak
Safety Emporium
Savillex Corporation
Solo Containment

Logistics

NNE Pharmaplan India Limited
AndersonBrecon
BioConvergence, LLC
ESS Ltd.
Intelleflex
Modality Solutions, LLC
New Wayz Consulting Ltd.
Sharp Clinical Services
XERIMIS, Inc.

Logistics/Supply Chain Management

AndersonBrecon
BioConvergence, LLC
ESS Ltd.
Intelleflex
New Wayz Consulting Ltd.
Sharp Clinical Services
XERIMIS, Inc.

Machinery Design and Construction

groninger USA L.L.C.
Techniserv, Inc.

Maintenance

Ace Control Systems Ltd.
Airy Filtration Co. Ltd.
Amcec, Inc.
Ateco Services AG
Avanceon
Azzur Group, LLC
Cascade Scientific, Inc.
Dart Controls, Inc.
Energy Engineering Co. Ltd.
ESS Ltd.
Fraser Engineering, Inc.
GenesisSolutions
GMP Templates
HOCHTIEF Solutions AG
Hofmeister Engineering, PC
Instalaciones ELUR, S.L.
International Coatings
Kelly Engineering Resources
Key Resin Company
M+W Group – Total Facility Solutions, Inc.
North Shore Mechanical Contractors, Inc.
Precis Engineering, Inc.
Production Modelling
Professional Project Services, Inc.
Protocol Link, Inc.
Redline PdM
Rogers Machinery Co., Inc.
Skanska
Spirax Sarco
STERIS Life Sciences
TATNUCK, Inc.
The Mundy Companies
TTE Laboratories

Manufacturing – API

Apache Stainless Equipment Corp.
Dec Group
Federal Equipment Company
Hermann WALDNER GmbH & Co. KG
Matcon Japan
Matcon Pacific Pty. Ltd.
Unimark Remedies Ltd.
Wayahead Systems

Manufacturing – Aseptic Fill/Finish

Adam Fabriwerk Pvt. Ltd.
American Plastic Technologies, Inc.
AMO (Hangzhou) Co. Ltd.
Bausch Advanced Technology Group
Dalton Pharma Services
DXC Consulting Ltd.
Federal Equipment Company
gammaSUPPLIES
Grand River Aseptic Manufacturing, Inc.
MAM Pharma Engineering Consultants
Optima pharma
PharmaBioSource, Inc.
PharmaSystems, Inc.
Rompharm Company
Shibuya Hoppmann Corporation
Unimark Remedies Ltd.
University of Iowa Pharmaceuticals
Vanrx Pharmasystems
Vetter Pharma International GmbH
Watson-Marlow Pumps Group

Manufacturing – Generics

Rompharm Company
Stevens Pharmaceutical Equipment Industries
Tapemark
Unimark Remedies Ltd.

Manufacturing – High Containment Operations

Camfil Farr Air Pollution Control
CDM
Class Biologically Clean Ltd.
Dec Group
Extract Technology Ltd.
Federal Equipment Company
Gerteis Maschinen + Processengineering AG
Isolation Systems, Inc.
Jacobs/Wyper Architects, LLP
M. Braun
PharmaConsult Us, Inc.
Powder Systems Ltd. (PSL)
Russell Finex, Inc.
seepex, Inc.
Stevens Pharmaceutical Equipment Industries
University of Iowa Pharmaceuticals

Manufacturing – Laboratory Equipment

ARS/Beverly Pacific Sterilizers
Bahnson Environmental Specialties, LLC
Bioquell, Inc.
Buchi Pilot Plant & Reactors Systems
Buss-SMS-Canzler GmbH
Dagard Clean Room
ETA Process Instrumentation
Exergy, LLC
Fedegari Autoclavi SpA
Freund-Vector Corporation
Getinge-La Calhene
HEMCO Corporation
Microzone Corporation
Okolab: Live Cell Microscopy
PharmaSystems, Inc.
Pharmatron, Inc.
Russell Finex, Inc.
Shimadzu Scientific Instruments
STERIS Life Sciences
Thieme Corporation
Watson-Marlow Pumps Group

Manufacturing – Other

Aquafine Corporation
Arc Machines, Inc.
Astech Projects
Budzar Industries
Catalent Pharma Solutions
CRANE ChemPharma Flow Solutions
Deerland Enzymes
Enerquip, LLC
Exergy, LLC
Federal Equipment Company
Glenroy, Inc.
Hanovia
Laserage
MAM Pharma Engineering Consultants
Michelle Marketing
PharmaBioSource, Inc.
Precision Polymer Engineering Ltd.
Robbins & Myers Process Solutions Group
Sabin Metal Corporation
Schenck Process
Sterling, Inc.
Trace Analytics, LLC

Manufacturing Equipment and Supplies

Adam Fabriwerk Pvt. Ltd.
Buffalo Air Handling
Contained Technologies, LLC
K-Tron G.B. Ltd.
Matcon Pacific Pty. Ltd.
Nikka Densok USA, Inc.
Romaco FrymaKoruma
Spirax Sarco

Materials Analysis

B&W Tek, Inc.
Chemir - A Division of Evans Analytical Group
CoreRx, Inc.
Fluid Imaging Technologies, Inc.
Outokumpu Stainless Plate
Q Laboratories, Inc.
Rigaku Raman Technologies

Medical Devices

Ashvins Group, Inc.
Ceramaret SA
Dynarex Corporation
EAG Life Sciences
Laserage
New Wayz Consulting Ltd.
Plainfield Precision
PRISYM ID

Medical/Clinical Studies

HealthCore, Inc.

Methods Development

Actlabs
Associates of Cape Cod, Inc.
Avid Bioservices, Inc.
Bureau Veritas North America, Inc.
Ceutical Laboratories, Inc.
Chemical Solutions Ltd.
Dalton Pharma Services
EAG Life Sciences
Frontage Laboratories, Inc.
HealthCore, Inc.
Polymer Solutions
Q Laboratories, Inc.
STEXCON

Methods Validation

Polymer Solutions
ValSource, LLC

Microbiological Testing

Azzur Labs, LLC
Associates of Cape Cod, Inc.
Azbil BioVigilant
Microbiology & Quality Associates, Inc.
Perritt Laboratories
Q Laboratories, Inc.
Rapid Micro Biosystems
Skytech Systems (I) Pvt. Ltd.
Technical Safety Services
TRI Air Testing, Inc.

Mixing and Blending

A & M Process Equipment Ltd.
Benz Technology International, Inc.
Dart Controls, Inc.
Dec Group
GlobePharma, Inc.
K-Tron G.B. Ltd.
Matcon China
Matcon Japan
Matcon USA
Romaco FrymaKoruma
SPX Flow Technology

Mixing and Granulating Equipment

A & M Process Equipment Ltd.
Fluid Air
Glatt Air Techniques, Inc.
LCI Corporation
Matcon France & Germany
Matcon Pacific Pty. Ltd.

Nonclinical Research

ChanTest Corporation
Vanta Bioscience, LC

Operations/Manufacturing

Anguil Environmental Systems, Inc.
Business Horizons
Control Micro Systems, Inc.
CRANE ChemPharma Flow Solutions
Dart Controls, Inc.
Laces Farma
Michelle Marketing
Parsec Automation
PharmaBioSource, Inc.
Pharmatron, Inc.
Production Modelling
Tapemark
Thermo Scientific – Material Characterization
TiPS Incorporated
Zarpac, Inc.

Other

A+ Secure Packaging
Access Creative Group
Aquafine Corporation
Arc Machines, Inc.
Astech Projects
ATC, Inc. - Advanced Test Concepts, Inc.
Budzar Industries
Catalent Pharma Solutions
Ceramaret SA
CRANE ChemPharma Flow Solutions
Deerland Enzymes
Enerquip, LLC
Exergy, LLC
Federal Equipment Company
Gemini Data Loggers
Glenroy, Inc.
Hanovia
Kelly Services
Laserage
MAM Pharma Engineering Consultants
Meriam Process Technologies
Michelle Marketing
Multisorb Technologies
nora systems, Inc.
PharmaBioSource, Inc.
Plascore, Inc.
Precision Polymer Engineering Ltd.
Process Plus, LLC
Robbins & Myers Process Solutions Group
Sabin Metal Corporation
Schenck Process
Sterling, Inc.
Ticona Engineering Polymers
Trace Analytics, LLC

Packaging – Anti-Counterfeiting

Access Creative Group
AlpVision SA
Covan Systems
InfraTrac
MNEMONICS, Inc.

Packaging – Blister

A+ Secure Packaging
Marchesini Group S.p.A.
Omori Machinery Co. Ltd.
Ruspak Corp., Inc.
XERIMIS, Inc.

Packaging – Blister – Cold Form

XERIMIS, Inc.

Packaging – Capsules

Capmatic Ltd.
NJM Packaging
OPTIMA pharma GmbH
Qualicaps
XERIMIS, Inc.

Packaging – Clinical Trials

AndersonBrecon
GA International, Inc.
Kirby Lester

Packaging – Consultants

Cold Chain Technologies, Inc.
Noblitt & Rueland
Robert C. Vincek Design Associates, LLC

Packaging – Creams and Ointments

Marchesini Group S.p.A.

Packaging – Design and Testing

Perritt Laboratories

Packaging – Development

Cold Chain Technologies, Inc.
Omori Machinery Co. Ltd.

Packaging – Electronic Pedigree

Intelleflex
NJM Packaging

Packaging – Equipment – Custom

Atlas Copco Compressors
Cozzoli Machine Company
Dividella Pharma Technology Solutions
Isthmus Engineering & Manufacturing
NJM Packaging
Optima pharma
Technical Engineering Ltd.

Packaging – Filling

Capmatic Ltd.
Chase-Logeman Corporation
Cozzoli Machine Company
Filamatic
IMA Life North America, Inc.
Kirby Lester
M&O Perry Industries, Inc.
NJM Packaging
OPTIMA pharma GmbH
PallayPack
Rommelag USA, Inc.
Shibuya Hoppmann Corporation

Packaging – Form/Fill/Seal

A+ Secure Packaging
Glenroy, Inc.
Labels, Inc. / Flexprint
Marchesini Group S.p.A.
Omori Machinery Co. Ltd.
PolyCine GmbH
Rommelag USA, Inc.
Ruspak Corp., Inc.
Weiler Engineering, Inc.

Packaging – Injectables

Air-Tite Products Co.
AWS Bio-Pharma Technologies
Capmatic Ltd.
Dividella Pharma Technology Solutions
Grand River Aseptic Manufacturing, Inc.
NJM Packaging
Optima pharma
OPTIMA pharma GmbH
Vanrx Pharmasystems
Weiler Engineering, Inc.

Packaging – Labels

GA International, Inc.
Innovatum, Inc.
Labels, Inc. / Flexprint
Nuceria Adesivi
PRISYM ID

Packaging – Liquids

Filamatic
M&O Perry Industries, Inc.
Marchesini Group S.p.A.
OPTIMA pharma GmbH
Rommelag USA, Inc.
Ruspak Corp., Inc.

Savillex Corporation
Weiler Engineering, Inc.

Packaging – Parenterals

Dividella Pharma Technology Solutions
Modality Solutions, LLC
NJM Packaging
PallayPack
PolyCine GmbH
Rommelag USA, Inc.
ZebraSci, Inc.

Packaging – Powders

Cozzoli Machine Company
Matcon France & Germany
Matcon Ltd.
Matcon USA
PolyCine GmbH
Ruspak Corp., Inc.

Packaging – RFID Labeling

Nuceria Adesivi

Packaging – Services - Other

A+ Secure Packaging
Access Creative Group
Multisorb Technologies
Process Plus, LLC

Packaging – Solid Dosage

A+ Secure Packaging
Matcon China
Matcon Japan
Matcon Ltd.
NJM Packaging
Omori Machinery Co. Ltd.
PallayPack

Packaging – Unit Dosage

Dividella Pharma Technology Solutions

Packaging Equipment

Absolute Handling Systems Ltd.
ASCO Numatics
Bausch Advanced Technology Group
BellatRx, Inc.
Bosch Packaging Technology
Brevetti Angela S.R.L.
Capmatic Ltd.
Changeover.com
Control Micro Systems, Inc.
Dabrico, Inc.
Dividella Pharma Technology Solutions
DJS Enterprises
Getinge-La Calhene
groninger USA, L.L.C.
Isthmus Engineering & Manufacturing
ITCM
Kirby Lester
M&O Perry Industries, Inc.
MAM Pharma Engineering Consultants
Marchesini Group S.p.A.
MNEMONICS, Inc.
Nikka Densok USA, Inc.
NJM Packaging
Omori Machinery Co. Ltd.
Shibuya Hoppmann Corporation
Stevens Pharmaceutical Equipment Industries
Techceuticals

Packaging Materials

Access Creative Group
Degage Corp.
Glenroy, Inc.
Labels, Inc. / Flexprint
Multisorb Technologies
Nuceria Adesivi
PolyCine GmbH
Qorpak
Ticona Engineering Polymers

Packaging Supplies

Degage Corp.
Qorpak

Photo-stability

Bahnson Environmental Specialties, LLC

Pilot Plants

Buchi Pilot Plant & Reactors Systems
CE&IC
em-tec Flow Technology, LP
GEA Lyophil GmbH
GSC Engineering, Inc.
MagnaSafe International
Pope Scientific, Inc.
SABArchitects, Inc.
Sepratech International
The Hart Companies
Thermo Scientific – Material Characterization

Pilot-Scale Filling

enviroflo
Grand River Aseptic Manufacturing, Inc.

Plant Engineering

GenesisSolutions
Hargrove Engineers + Constructors
Key Resin Company
Nicos Group, Inc.
North Shore Mechanical Contractors, Inc.
QSPEC Solutions, Inc.
Rogers Machinery Co., Inc.

Pre-formulation

Patheon, Inc.

Process Analytical Technology (PAT)

CAI (Shanghai) Engineering Consulting Co. Ltd.
Commissioning Agents International
Commissioning Agents International Singapore Pte. Ltd.
Commissioning Agents Ireland Ltd.
Commissioning Agents Puerto Rico, LLC
Commissioning Agents, Inc.
Fluid Imaging Technologies, Inc.
FOSS NIRSystems, Inc.
GEA Lyophil GmbH
GEA Pharma Systems - Collette
Gerteis Maschinen + Processengineering AG
M+W Automation
Malawer & Associates Consulting, LLC
Mettler-Toledo Thornton, Inc.
MKS Instruments, Inc.
Parsec Automation
Physical Sciences, Inc.
Rigaku Raman Technologies
Svanholm.com
Swagelok
TSI, Inc.
Tunnell Consulting, Inc.
Uhlmann VisioTec GmbH
Watson-Marlow Pumps Group
Werum Software & Systems AG
Yokogawa
Zarpac, Inc.

Process Control/ Automation

Bürkert Fluid Control Systems
NNE Pharmaplan, Inc.
NNE Pharmaplan (Tianjin) Co. Ltd.
AIV Solutions
Applied Control Engineering, Inc.
Ausenco PSI
Avanceon
BatchControl Ltd.
Beamex, Inc.
Broadley-James Ltd.
Burns & McDonnell
Burns Engineering
Dart Controls, Inc.
E2i
Fike
FOSS NIRSystems, Inc.
Hardy Process Solutions
Harrington Pure
Huffman Engineering, Inc.
K-Tron G.B. Ltd.
Kereon AG
M+W Automation
MagneMotion
MKS Instruments, Inc.
optek-Danulat, Inc.
Pentair Sudmo
Praxair, Inc.
seepex, Inc.
Sensor Technology Ltd.
Spirax Sarco
Swagelok
TiPS Incorporated
Yokogawa

Process Design

NNE Pharmaplan A/S
NNE Pharmaplan AB
NNE Pharmaplan, Inc.
NNE Pharmaplan Sdn. Bhd.
OOO NNE Pharmaplan
Burns & McDonnell
CE&IC
DEC-USA
DME Alliance Engineering Consultants
Electrol Specialties Co.
Hargrove Engineers + Constructors
Hyde Engineering + Consulting, Inc.
LifeTek
M+W Group
Manrochem Limited
Robbins & Myers Process Solutions Group
Talboom PharmaChem NV
The Hart Companies

Process Development/ Scale-Up Services

Avid Bioservices, Inc.
Biomanufacturing Training and Education Center (BTEC)
Meissner Filtration Products, Inc.

Process Gases

Brooks Instrument
GMP Piping, Inc.
IN USA, Inc.
Praxair, Inc.
Swagelok
Trace Analytics, LLC

Process R&D

Alden

Process Validation Studies

OOO NNE Pharmaplan
Advanced Biomedical Consulting (ABC), LLC
AL Engineering
GE Measurement & Control
Modality Solutions, LLC
Pharmatech Associates, Inc.
ProPharma Group
TRAQuE Pte. Ltd.

Processing Equipment

Top Line Process Equipment Company
accumac Ltd.
Alfa Laval
Alfa Laval Reactor Technology
AlphaBio, Inc.
AOIP SAS
APV, An SPX Brand
Ateco Services AG
Atlas Copco Compressors
Bausch + Stroebel
Benz Technology International, Inc.
Brooks Instrument
Buchi Pilot Plant & Reactors Systems
Buffalo Air Handling
Buss-SMS-Canzler GmbH
DCI, Inc.
DJS Enterprises
Donaldson Torit
Dow Corning Corporation
Electrol Specialties Co.
Enerquip, LLC
ETA Process Instrumentation
Exergy, LLC
Exigo Manufacturing
Fab-Tech, Inc.
Fluid Air
FPS Food and Pharma Systems
gammaSUPPLIES
GEA Pharma Systems
GEA Tuchenhagen GmbH
Gemu Valves Limited
Glatt Air Techniques, Inc.
GlobePharma, Inc
GMP Systems, Inc.
Hardy Process Solutions
HOSOKAWA ALPINE Aktiengesellschaft
Hydro-Thermal Corp
IMA Life North America, Inc.
Isthmus Engineering & Manufacturing
K-Tron (Shanghai) Co. Ltd.

K-Tron Pitman
K-Tron Salina
LCI Corporation
Lee Industries, Inc.
Leistritz
LJ Star, Inc.
Loedige Maschinenbau GmbH
Luthra Industrial Engineering Corporation
MagnaSafe International
Matcon China
Matcon Pacific Pty. Ltd.
Microfluidics
Millrock Technology, Inc.
Pentair Sudmo
Pope Scientific, Inc.
Quadro Engineering Corp.
Qualicaps
REMCON Plastics
Rogers Machinery Co., Inc.
Romaco FrymaKoruma
Russell Finex, Inc.
S3 Process Limited
Schenck Process
Shanghai Ritai Medicine Equipment Project Co. Ltd
Steriflow Valve
Symetix
The Fitzpatrick Company
VNE Corporation
WCB, An SPX Brand

Processing and Manufacturing

Allegheny Bradford Corporation
Aquafine Corporation
AWS Bio-Pharma Technologies
FlexFit Hose
GEA Westfalia Separator
Gerteis Maschinen + Processengineering AG
Jordan Valve
Luthra Industrial Engineering Corporation
Matcon France & Germany
Matcon Pacific Pty. Ltd.
MECO
Rogers Machinery Co., Inc.
Russell Finex, Inc.
Schenck Process
Steriflow Valve
Thermo Scientific – Material Characterization
Vaisala
Wayahead Systems

Product Development

Alden
Outokumpu Stainless Plate
Ticona Engineering Polymers

Project Management

NNE Pharmaplan AB
NNE Pharmaplan AG
NNE Pharmaplan India Limited
NNE Pharmaplan (Tianjin) Co. Ltd.
AllianzOne Private Limited
Applied Control Engineering, Inc.
Ashvins Group, Inc.
Cold Chain Technologies, Inc.
Compliance Control Ltd.
CTG (UK) Limited
Global Research Services, LLC
GMP Templates
Hach Company
M+W Group
M+W Singapore Pte. Ltd.
MAM Pharma Engineering Consultants
MIVADO GlobalPerformance, Inc.
Particle Measuring Systems
PM Greene Engineers
PM Group
ProPharma Group
QPharma, Inc.
Sharp Clinical Services
SpecLine Consulting, Inc.
STEXCON
Sweett Group

Protein Extraction/ Purification

GEA Westfalia Separator

Pumps and Pump System

Alfa Laval
APV, An SPX Brand
Ashberry Water
Burt Process Equipment, Inc.
Ceramaret SA
Fristam Pumps USA
McFlusion Corp
North Shore Mechanical Contractors, Inc.
seepex, Inc.
SPX Flow Technology
Top Line Process Equipment Company
WCB, An SPX Brand
Wintek Corporation

Purification

Burt Process Equipment, Inc.
GEA Westfalia Separator
MECO
Sartorius Stedim Biotech

Quality Assurance/Control

AICOS Technologies Ltd.
Astro Pak
Beamex, Inc.
Document Center, Inc.
FOSS NIRSystems, Inc.
GE Analytical Instruments
GE Measurement & Control
GMP Templates
Infodynamics s.r.l.
Integrated Compliance Solutions, LLC
MNEMONICS, Inc.
optek-Danulat, Inc.
Pharmatron, Inc.
Provalidus
PSC Asia
Rapid Micro Biosystems
Rescop BV
Trace Analytics, LLC
Tunnell Consulting, Inc.
Vaisala

R and D Services

Alden
ENV Services, Inc.
Sharp Clinical Services
Raw Materials Analysi
B&W Tek, Inc.
Chemir - A Division of Evans Analytical Group
CoreRx, Inc.
Outokumpu Stainless Plate
Q Laboratories, Inc.
Rigaku Raman Technologies
Warsash Scientific

Regulatory Affairs/ Compliance/ Consultants

NNE Pharmaplan, Inc.
Advanced Biomedical Consulting (ABC), LLC
Amcec, Inc.
Business & Decision Life Sciences
Christy Pavano Consulting
CTG
Document Center, Inc.
DynPort Vaccine Company LLC, A CSC Company
Foster Wheeler
Integrated Compliance Solutions, LLC
New Wayz Consulting Ltd.
Prime Technologies, Inc.
Protocol Link, Inc.
PSC Asia
QPharma, Inc.
SeerPharma (Singapore) Pte. Ltd.
Specialty Operations Solutions, Inc.
The Williamsburg Group, LLC
VPCI, Inc.

Scale-Up

Alden
Alfa Laval Reactor Technology
Avid Bioservices, Inc.
Biomanufacturing Training and Education Center (BTEC)
GSC Engineering, Inc.
Meissner Filtration Products, Inc.
PharmaCore, Inc.
Rozembersky Group, Inc.

Screening – Classifying

HOSOKAWA ALPINE Aktiengesellschaft

Separation Science

GEA Westfalia Separator

Serialization

Access Creative Group
Innovatum, Inc.
Uhlmann VisioTec GmbH

Shipping

Modality Solutions, LLC

Site Selection

Laces Farma

Size Reduction

Dabrico, Inc.
DEC-USA
Fluid Air
FPS Food and Pharma Systems
HOSOKAWA ALPINE Aktiengesellschaft
Microfluidics
Quadro Engineering Corp.
S3 Process Limited
Sterling, Inc.
The Fitzpatrick Company

Software/Hardware Products

PSC Biotech
AlpVision SA
ARX
Ashvins Group, Inc.
Blue Mountain Quality Resources, Inc.
NetDimensions (UK) Limited
PleaseTech Ltd.
Prime Technologies, Inc.
Rescop BV
Simplyfeye Softwares (P) Ltd.
TiPS Incorporated

Spectroscopy

B&W Tek, Inc.
FOSS NIRSystems, Inc.
IN USA, Inc.
Rigaku Raman Technologies
Shimadzu Scientific Instruments

Spray Drying

Emerson Resources, Inc.
Praxair, Inc.
Spraying Systems Co.
SPX Flow Technology

Stability Studies

Actlabs
BioConvergence, LLC
Cincinnati Sub-Zero
Masy Systems, Inc.
PharmIdea

Sterile Filling

Bausch + Stroebel
Bioquell, Inc.
Chase-Logeman Corporation
Cozzoli Machine Company
groninger USA, L.L.C.
IMA Life North America, Inc.
Lyophilization Technology, Inc.
M&O Perry Industries, Inc.
PharmaSystems, Inc.
Vanrx Pharmasystems

Sterile Products Processing

Belimed, Inc.
Dec Group
gammaSUPPLIES
Meissner Filtration Products, Inc.
SKAN AG
The Williamsburg Group, LLC
Weiler Engineering, Inc.

Sterility Testing

FPS Food and Pharma Systems
GE Measurement & Control
Lives International
M. Braun
ProSys Containment & Sampling Technology
SKAN AG

Sterilization

Agalloco & Associates, Inc.
American Plastic Technologies, Inc.
ARS/Beverly Pacific Sterilizers
Belimed, Inc.
Bioquell, Inc.
Colder Products Company
Endress+Hauser
Environmental Water Systems
ETC Sterilization Systems
Fedegari Autoclavi SpA
Fike
FlexFit Hose
Fristam Pumps USA
GEA Lyophil GmbH
GESTRA AG
Getinge Life Science Americas

HallTech
Hyde Engineering + Consulting, Inc.
Hydro-Thermal Corp
IN USA, Inc.
IWT srl
Jordan Valve
M+W Group – Total Facility Solutions, Inc.
McFlusion, Inc.
Meissner Filtration Products, Inc.
Nicos Group, Inc.
PSC Asia
Sixlog
Skytech Systems (I) Pvt. Ltd.
Spraying Systems Co.
STERIS Life Sciences
Telstar
Telstar Life Sciences
Telstar North America, Inc.
Thermal Compliance Ltd.
WCB, An SPX Brand

Storage

Masy Systems, Inc.
Salsbury Industries - Lockers.com

Supplier – Equipment

Matcon Ltd.
Absolute Handling Systems Ltd.
Acquire Automation
AGRU Kunststofftechnik GmbH
Alfa Laval
Anguil Environmental Systems, Inc.
Atlas Copco Compressors
BellatRx, Inc.
Bioquell, Inc.
BMT USA, LLC
Budzar Industries
Buffalo Air Handling
Burt Process Equipment, Inc.
Contained Technologies, LLC
Cozzoli Machine Company
DCI, Inc.
DENSO Robotics
Donaldson Torit
Enerquip, LLC
ETA Process Instrumentation
Exigo Manufacturing
GEA Pharma Systems - Collette
Gemu Valves Limited
GESTRA AG
Getinge Life Science Americas
Glatt Air Techniques, Inc.
Heleon BV
Hurst Corporation
Isthmus Engineering & Manufacturing
IWT srl
Jung Gummitechnik GmbH
K-Tron (Shanghai) Co. Ltd.
Kraemer US, LLC
LCI Corporation
LJ Star, Inc.
Luthra Industrial Engineering Corporation
Matcon Japan
Matcon USA
MECO
Microfluidics
Multisorb Technologies
New England Controls, Inc.
Nextteq, LLC
Quadro Engineering Corp.
Qualicaps
REMCON Plastics
RPA
S3 Process Limited
Safety Emporium
Schenck Proces
Sepratech International
Shanghai Ritai Medicine Equipment Project Co. Ltd.
Shickel Corporation
Symetix
Terracon Corporation
The Fitzpatrick Company
Wintek Corporation

Supplier – Fine Chemicals

AMCOL International

Supplier – Glass

LJ Star, Inc.

Supplier – Primary Packaging Materials

Access Creative Group
Degage Corp.
Labels, Inc. / Flexprint
Multisorb Technologies
PolyCine GmbH

Supplier – Raw Materials

Outokumpu Stainless Plate

Supplier – Secondary Packaging Materials

Access Creative Group

Sustainability/Waste Management

PM Greene Engineers
Spirax Sarco Ltd.

Sustained Release Delivery Systems

CoreRx, Inc.

Syringe Filling

Bausch + Stroebel
Brevetti Angela S.R.L.
groninger USA, L.L.C.
Lyophilization Technology, Inc.
Optima pharma

System Integration

AlphaBio, Inc.
Applied Control Engineering, Inc.
Astech Projects
DAI
GMP Systems, Inc.
Huffman Engineering, Inc.
K-Tron Pitman
K-Tron Salina
New England Controls, Inc.
NJM Packaging
NZ Controls Ltd.
Optimation
RJR Technical Services
Sartorius Stedim Biotech
seepex, Inc.
SPX Flow Technology
Techniserv, Inc.

Tablet Presses

GEA Process Engineering
accumac Ltd.
Fette Compacting
GEA Pharma Systems
GlobePharma, Inc.
Huxley Bertram
IPR, Inc.
K-Tron (Shanghai) Co. Ltd.
KORSCH America, Inc.
Techceuticals

Technology Transfer

Christy Pavano Consulting
Laces Farma
Manrochem Limited
Modality Solutions, LLC
Validation Technologies, Inc.

Testing Laboratory

ATC Inc. - Advanced Test Concepts, Inc.
Chemical Solutions Ltd.
Christy Pavano Consulting
Cincinnati Sub-Zero
Cold Chain Technologies, Inc.
CSZ Testing Services
ENV Services, Inc.
Fike
Perritt Laboratories
Polymer Solutions
Q-Lab Corporation
Trace Analytics, LLC

Thermoplastic Extrusion

AdvantaPure
Saint-Gobain Performance Plastics

Thermoplastic Molding

AdvantaPure
Plainfield Precision
Saint-Gobain Performance Plastics
Value Plastics, a Nordson Company

Torque Testing

AMETEK Test & Calibration Instruments
Pharmatron, Inc.
Sensor Technology Ltd.

Trace Metal Analysis – ICP

Chemical Solutions Ltd.

Traditional Pharmaceuticals

Laces Farma

Training

Agalloco & Associates, Inc.
AICOS Technologies Ltd.
Astro Pak
cGMP Validation, LLC
Changeover.com
Controlled Contamination Services
CTG
David H. Artiss and Associates, Inc.
DynaGM
Empowerment Quality Engineering Ltd.
Infodynamics s.r.l.
Kereon AG
Laces Farma
Lighthouse Worldwide Solutions
NetDimensions (UK) Limited
Noblitt & Rueland
NSF-DBA
PSC Asia
QPharma, Inc.
Rozembersky Group, Inc.
SeerPharma (Singapore) Pte. Ltd.
Specialty Operations Solutions, Inc.
ValSource, LLC

Training: CGMP/HPB/FDA Compliance

Astro Pak
cGMP Validation, LLC
CTG
David H. Artiss and Associates, Inc.
Infodynamics s.r.l.
NetDimensions (UK) Limited
NSF-DBA
PSC Asia
QPharma, Inc.
Specialty Operations Solutions, Inc.

Training: Process Validation

cGMP Validation, LLC
DynaGMP
NetDimensions (UK) Limited

Training: Safety

Controlled Contamination Services

Validation – Clinical

arnoult.org

Validation – Equipment Cleaning

Validation, Inc.
cGMP Validation, LLC
DynaGMP
McFlusion, Inc.
Microbiology & Quality Associates, Inc.
STERIS Life Sciences
Validation Technologies, Inc.

Validation – Filtration

Camfil Farr Australia Pty. Ltd.
Harrington Pure

Validation – Manufacturing

NNE Pharmaplan AB
Validation, Inc.
Agalloco & Associates, Inc.
cGMP Validation, LLC
Christ Nishotech Systems Pvt. Ltd.
DXC Consulting Ltd.
GE Measurement & Control
Kirby Lester
KVS Technologies
MIVADO GlobalPerformance, Inc.
Pharma Insight, Inc.
Provalidus
US Data Management
Validation Technologies, Inc.
Wayahead Systems

Validation – Services (Qualification/ Commissioning)

Azzur Group, LLC
Nivasoft, Inc.
NNE Pharmaplan Consultoria Ltda.
NNE Pharmaplan GmbH
NNE Pharmaplan, Inc.
NNE Pharmaplan NV
NNE Pharmaplan sas
NNE Pharmaplan Sdn. Bhd.
NNE Pharmaplan (Tianjin) Co. Ltd.
OOO NNE Pharmaplan
PSC Biotech
Validation, Inc.
Advanced Biomedical Consulting (ABC), LLC
AIV Solutions

AL Engineering
Applied Control Engineering, Inc.
Bahnson Environmental Specialties, LLC
Cascade Scientific, Inc.
Century 3 (Shanghai), Inc.
cGMP Validation, LLC
Christ Nishotech Systems Pvt. Ltd.
CTG
CTG (UK) Limited
Deloitte
Empowerment Quality Engineering Ltd.
ETC Sterilization Systems
G.M.Project
GE Analytical Instruments
Glatt Air Techniques, Inc.
HOCHTIEF Solutions AG
Infodynamics s.r.l.
KVS Technologies
Masy Systems, Inc.
Micro-Clean, Inc.
Microbiology & Quality Associates, Inc.
Optimation
Performance Validation
PharmaSys, Inc.
Pharmatech Associates, Inc.
Process Plus, LLC
PROGMP SAS
PSC Asia
QPharma, Inc.
Rees Scientific
Rescop BV
RJR Technical Services
Sartorius Stedim Biotech
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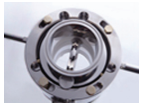

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